IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

BLUE CROSS BLUE SHIELD ASSOCIATION, et al.	:	CIVIL ACTION
	:	No. 13-4663
v.	:	
GLAXOSMITHKLINE LLC	:	

MEMORANDUM

Juan R. Sánchez, C.J. **September 30, 2019**

Plaintiffs, 38 private health insurance companies that purchased billions of dollars' worth of adulterated pharmaceutical drugs from Defendant GlaxoSmithKline LLC (GSK), bring claims under the Racketeer Influenced and Corrupt Organizations Act (RICO) and Pennsylvania law, alleging they purchased the drugs at issue based on GSK's misrepresentations that the drugs were manufactured in accordance with the Food and Drug Administration's "current Good Manufacturing Practices."[1] Plaintiffs claim the adulterated drugs were worthless and had they known of the adulteration, they would not have included the drugs in their formularies. GSK has moved for summary judgment as to all claims pursuant to Federal Rule of Civil Procedure 56. Because Plaintiffs' RICO (Counts I – III) and unjust enrichment (Count VII) claims fail as a matter of law, GSK's motion for summary judgment will be granted as to those claims. The motion will be denied as to Plaintiffs' remaining claims for fraud (Count IV), civil insurance fraud pursuant to 18 Pa. Cons. Stat. § 4117 (Count V), negligent misrepresentation (Count VI), and breach of express warranty (Count VIII), and breach of implied warranty of merchantability (Count IX), which present genuine issues of material fact for trial.

[1] At the time of filing, 41 private health insurance companies were named as plaintiffs in this action. Since then, three plaintiffs—Blue Cross of Idaho Health Service, Inc., Health Care Services Corporation, and Horizon Blue Cross Blue Shield of New Jersey- have settled with GSK.

BACKGROUND[2]

A. Current Good Manufacturing Practices and the Food and Drug Administration's Enforcement Authority

The Food and Drug Administration (FDA) oversees compliance and enforcement of the federal Food, Drug and Cosmetic Act (FDCA), 21 U.S.C. § 301, et seq. Pursuant to its rulemaking authority, the FDA promulgates "current Good Manufacturing Practices" (cGMPs). *See* 21 C.F.R. § 210-11. CGMPs address a variety of aspects of the drug manufacturing process, such as personnel, facilities, equipment, packaging, distribution, laboratory controls, and record keeping. *See id.* If a manufacturer does not comply with cGMPs, any drug it makes is considered "adulterated" under the FDCA and may not be distributed or sold in the United States. *See* 21 U.S.C. §§ 331(a), 351(a)(2)(B). The fact that a drug was manufactured under conditions not in compliance with cGMPs, however, "does not mean that there is necessarily something wrong with the drug[]." GSK's Mot. for Summ. J. (GSK Mot.) Ex. 1. In fact, "there is some level of [c]GMP nonconforming product" on the market at any given time. *Id.* Ex. 8, at 299:11-300:3. And in most instances, the FDA advises consumers currently taking such drugs to not interrupt their drug therapy. *See id.* Ex. 1.

To ensure drugs are manufactured in compliance with cGMPs, the FDA has various regulatory enforcement tools to address violations. The FDA's response to cGMP violations depends on the nature of those violations and on the specific drugs involved. *See id.* As part of its oversight duties, the FDA inspects drug manufacturing facilities and reviews documentation to verify the manufacturer's compliance with cGMP requirements. *See* 21 U.S.C. § 374. In instances

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[2] In evaluating a motion for summary judgment, a court must "view the facts in the light most favorable to the non-moving party and must make all reasonable inferences in that party's favor." *Hugh v. Butler Cty. Family YMCA*, 418 F.3d 265, 267 (3d Cir. 2005). Except where noted, the facts presented herein are undisputed. The Court further notes that the citations to the voluminous record in this case are to the exhibits as numbered and attached to the parties' submissions.

where the FDA observes a "significant objectionable condition relating to products and/or processes, or other violations of the [FDCA]," the FDA issues a "Form 483" notice, notifying "the inspected establishment's top management in writing" of the observations. GSK Mot. Ex. 3, at § 5.2.3. If a manufacturer fails to address the observations made in the Form 483 notice, the FDA may issue a warning letter when the violations are of regulatory significance. *See id.* Ex. 4, at 3. The FDA issues numerous warning letters each year. *See, e.g* , *id.* Ex. 5, at 1 (noting from 2000 to 2004, the FDA issued an average to 53 cGMP-related warning letters each year).

If the manufacturer does not correct the deficiencies identified in the warning letter, the FDA may request that the manufacturer voluntarily recall the drugs it sold which did not meet cGMP regulations. *See id.* Ex. 4, at 3. The FDA may also seize affected drugs or enjoin the manufacturer from producing the drug in question. *See id.*; *see also* 21 U.S.C. §§ 332, 334. If the FDA proceeds by way of a seizure or injunction, it may enter into a consent decree with the manufacturer requiring the manufacturer to take certain steps to correct the cGMP violations or stop manufacturing at the offending plant. The FDA has the discretion to choose its enforcement mechanism, and "[t]he FDA's decision-making process with respect to seizures and consent decrees is complex and involves a variety of legal and practical considerations." *See* GSK Mot. Ex. 13, at ¶ 10.

B. SB Pharmco and the Cidra Plant

From 2000 to 2005 (the Relevant Period), SB Pharmco Puerto Rico Inc. (SB Pharmco) owned and operated a pharmaceutical manufacturing plant in Cidra, Puerto Rico (the Cidra Plant). *See* Pls.' Resp. in Opp'n to Mot. for Summ. J. (Pls.' Opp'n) Ex. 5, at 126:9-17. Originally built in 1978 to manufacture a single drug, the Cidra Plant was manufacturing 267 different drugs by 2004. *See id.* Ex. 3 GSK-ECK-10-25620. Among the drugs SB Pharmco manufactured at the Cidra Plant were the seventeen drugs at issue in this case—Albenza, Avandia, Avandamet, Bactroban,

Compazine, Coreg, Denavir, Dibenzyline, Dyazide, Dyrenium, Factive, Horowitz, Kytril, Paxil IR, Paxil OS, Stelazine, and Thorazine (collectively, the At-Issue Drugs).[3] *See id.* Ex. 12, at 4-6.

SB Pharmco, a Puerto Rican corporation, and GSK, a Delaware Limited Liability Company, are both indirect subsidiaries of GlaxoSmithKline plc, a United Kingdom holding company. *See id.* Ex. 2. SB Pharmco was responsible for manufacturing the At-Issue Drugs while GSK was responsible for marketing and selling the At-Issue Drugs in the United States. Plaintiffs' contend a drug product's "label and other written material convey a drug company's assurance that its drugs are properly manufacture and conform to their representative properties."[4] *See* Pls.' Opp'n Ex. 142 ¶¶ 17, 36, 40, 40 n.18; *Id.* Ex. 18 at ¶ 14; *id.* Ex. 89, at 47:25-48:3. GSK marked products manufactured at the Cidra Plant as "best-in-class" and the "gold standard," and asserted their "superior potency, efficacy, and safety profile." *Id.* Ex. 143, at 161:14-17, 186:5-10, 131:6-12; 214:21-215:3.

C. Plaintiffs and Their Purchase of the At-Issue Drugs

Plaintiffs are 38 of the largest health insurance providers in the United States, collectively representing approximately 60% of the United States market for non-governmental health insurance. During the Relevant Period, Plaintiffs provided health insurance coverage pursuant to the terms of plan benefit contracts with plan sponsors, i.e., employers and individuals. *See* GSK Mot. Ex. 20, at ¶ 20; *id.* Ex. 21, at 103:15:23. Each plan sponsor "would have a contract that describes the services and the scope" of coverage provided under the plan and would be issued a

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[3] This fact is undisputed except to the extent GSK notes that some At-Issue Drugs were also manufactured at other facilities. *See* GSK's Resp. to Pls.' Statement of Material Facts ¶ 10.

[4] GSK disputes this fact, asserting Plaintiffs' expert Dr. David A. Kessler testified that a product label does not state whether a product was made in conformity with cGMPs. *See* GSK Resp. Statement of Material Facts Ex. 18, at 224:9-14 ("Q. Does the product label state that a product is made in conformity with current good manufacturing practices? A. No, but it says that a label has certain things about that and has to have . . . .").

"benefit plan document." *Id.* Ex. 22, at 76:8-14. Plaintiffs also provided services pursuant to "administrative services only" plans for self-insured, self-funded, and government plans. *See, e.g* , Pls.' Opp'n Ex. 148; *id.* Ex. 151.

During the Relevant Period, each Plaintiff maintained one or more formularies of prescription drugs, which provided the list of the drugs covered by the health benefit plans Plaintiffs administered. *See* Am. Compl. ¶ 181. Most Plaintiffs, during at least a portion of the Relevant Period, were advised by one or more Pharmacy and Therapeutics committees (P&T committee), which members typically included physicians and pharmacists.[5] *See id.* The P&T committees advised Plaintiffs on the content of their formularies, including whether to provide or discontinue coverage for a drug. In developing their recommendations, P&T committees typically reviewed information supplied by the drug's seller, as well as clinical and scientific studies. *See* Pls.' Opp'n Ex. 188, at 30:7-15; *id.* Ex. 152, at 251:11-20. For some Plaintiffs, the P&T committee worked with a third-party pharmacy benefit manager (PBM), which provided certain administrative services. In some cases, the PBM supplied the P&T committee with clinical information and recommended formularies, while in others, Plaintiffs would adopt formularies as

[5] Plaintiffs utilizing a P&T committee include: Aetna, Inc.; Amerigroup/HMS; AvMed Health Plans; BlueCross BlueShield of Alabama; Blue Cross Blue Shield Association; Blue Cross Blue Shield of Delaware; Blue Cross and Blue Shield of Florida, Inc.; Blue Cross and Blue Shield of Kansas City; Louisiana Health Service Indemnity Company d/b/a Blue Cross and Blue Shield of Louisiana; Blue Cross Blue Shield of Minnesota; BlueCross BlueShield of Tennessee; Blue Cross Blue Shield of Montana, Inc.; Connecticut General Life Insurance Company; Emblem Health; Group Health Cooperative; HealthNet, Inc.; Highmark Inc.; Highmark West Virginia, Inc. d/b/a Highmark Blue Cross Blue Shield West Virginia; Horizon Blue Cross Blue Shield of New Jersey; KPS Health Plans; Blue Cross Blue Shield of North Dakota d/b/a Nordian; Premera Blue Cross; Priority Health; The Regence Group; USAble Mutual Insurance Company d/b/a Arkansas Blue Cross and Blue Shield and HMO Partners; Inc. d/b/a Health Advantage; WellCare Health Plans, Inc.; Wellmark Health Plan of Iowa, Inc. and Wellmark Inc. d/b/a Wellmark Blue Cross and Blue Shield of Iowa; and Well Point, Inc.

developed by their PBM.[6] *See id.* Ex. 152, 222:24-223:18; *id.* Ex. 206, at 21:8-22:8; *id.* Ex. 207, at 122:23-123:11; *id.* Ex. 149, at 112:1-16; *id.* Ex. 201, at 70:17-71:2; *id.* Ex. 159, at 97:3-19, 98:13-25, 103:1-12.

During the Relevant Period, Plaintiffs most commonly operated "open formularies," which provided that "any drug that is an FDA-approved drug would be covered [or] eligible for coverage under the formulary," subject to exclusions in the plan benefit contract. *See* GSK Mot. Ex. 31, at 212:11-18. In an open formulary, "as a new [FDA-approved drug] would come out, it would automatically be added to the formulary." *Id.* Ex. 49, at 179:23-180:7. Plaintiffs' formularies generally provided varying tiers (or co-pay levels) for covered drugs.

Plaintiffs assert they had the ability to stop or restrict payments for FDA-approved drugs on an open formulary during the Relevant Period, through a wide-variety of enforcement mechanisms, including:

> (1) "NDC blocks," which freeze payments for drugs identified by National Drug Code number; (2) exclusions from coverage under the terms of the insurer's Summary of Plan Description; (3) prior authorization requirements; (4) "step edits," which bar payment for a particular drug unless treatment with another drug proves unsuccessful; (5) "tier management," which gives preferential coverage (e.g., lower co-pays) to some drugs over others; (6) quantity restrictions; (7) limits on prescriber authorizations; and (8) age and gender restrictions.[7]

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[6] The parties dispute whether Plaintiffs considered cGMP compliance when determining the content of their formularies or monitored covered drugs for cGMP violations. GSK asserts Plaintiffs "did not consider manufacturing issues . . . in making decisions regarding their formularies," GSK Statement of Undisputed Material Facts ¶ 55, and "[n]o plaintiff monitored for cGMP violations during the relevant period," *see id.* ¶ 56. Plaintiffs dispute this noting their corporate representatives have "repeatedly and consistently testified that decisions regarding their formularies were based on assurance that the At-Issue Drugs met cGMP requirements and were what they purported to be." *See* Pls.' Resp. to Def.'s Statement of Undisputed Material Facts 29.

[7] GSK disputes this fact arguing Plaintiffs had no authority or ability to stop or restrict coverage for FDA-approved drugs because doing so would breach Plaintiffs' contractual obligations with their plan sponsors.

See Pls.' Opp'n Ex. 208, at 3-4; *id.* Ex. 186, at ¶ 4 & n.6.

Through their formularies, Plaintiffs provided coverage for the At-Issue Drugs manufactured at the Cidra Plant during the Relevant Period.[8] Plaintiffs did not directly pay GSK for the cost of the At-Issue Drugs. Rather, pharmacies purchased prescription drugs from wholesalers, who bought them from GSK. Plaintiffs or their PBMs would then reimburse the pharmacy for the cost of the covered drugs pursuant to separate agreements to which GSK was not a party. *See* Am. Compl. ¶ 183 ("GSK caused each Plaintiff's employees or other agents to . . . process claims for payment for the At-Issue Drugs from pharmacies and pharmacy benefit managers."); *see also* GSK Mot. Ex. 47, at 104:6-7 ("[Blue Cross and Blue Shield of North Carolina] would pay the PBM, and the PBM would pay the pharmacy.").

D. FDA Inspections and cGMP Issues at the Cidra Plant

During the Relevant Period, the FDA inspected the Cidra Plant a total of nine times to check for cGMP violations. These inspections occurred on (1) February 10-March 7, 2000; (2) March 29-July 6, 2001; (3) February 7-April 10, 2002, (4) September 19-October 9, 2002; (5) March 17-19, 2003; (6) May 21-28, 2003; (7) October 7-December 2, 2003; (8) September 9-November 5, 2004; and (9) December 12, 2005-January 23, 2006. *See* GSK Mot. Ex. 6, at 11-16.

The FDA did not identify any cGMP violations warranting the issuance of a Form 483 notice in its first inspection ending on March 7, 2000. *See id.* Ex. 59, at GSK-ECK-4-5352. Following its second inspection ending on July 6, 2001, the FDA issued a Form 483 notice containing 23 observations regarding the Cidra Plant's manufacturing process. *See id.* Ex. 60, at

[8] The parties dispute whether GSK sought to influence insurers to place and maintain its drugs on the insurer's formulary. Plaintiffs contend "GSK made intensive efforts to ensure that its drugs were placed on insurers' formularies," Pls.' Statement of Material Facts ¶ 225, by methods such as assigning marketing employees to specific insurers, *see id.* ¶ 226-27, and tailoring clinical studies to match insurers' expectations, *see id.* ¶ 229. GSK disputes these assertions and alleges they are immaterial to the instant case.

GSK-ECK-4-5377. The July 6, 2001, Form 483 notice made observations relating to issues with the production of six of the At-Issue Drugs—Paxil OS, Compazine, Coreg, Dibenzyline, Stelazine, and Thorazine. *See generally id.* The FDA closed this inspection as "Voluntary Action Indicated," following a meeting with Cidra and GSK personnel on September 6, 2001, during which GSK represented that 18 of the 23 observations were corrected and the remaining five were in the process of being remedied. Pls.' Opp'n Ex. 45, at GSK-ECK-51-16132; *id.* Ex. 46, at GSK-ECK-4-58-59.

In its next inspection ending on April 10, 2002, the FDA issued another Form 483 notice listing 15 cGMP violation observations relating to the production of Avandia, Bactroban, Compazine, Paxil tablets, Paxil OS, and Thorazine. *See* GSK Mot. Ex. 62, at GSK-ECK-6-47267. Three months later, on July 1, 2002, the FDA issued a warning letter to SB Pharmco noting "inspectional findings revealed that your products Bactroban Ointment, Paxil Oral Suspension and Thorazine tablets are" not cGMP compliant and are "adulterated within the meaning of Section 501(a)(2)(B) of the [FDCA]." *See id.* Ex. 63, at GSK-ECK-4-851. At the conclusion of a follow-up inspection on October 9, 2002, the FDA issued a Form 483 notice identifying one manufacturing observation, which generally asserted the Cidra Plant was not following procedures designed to prevent microbiological contamination of drug products. *See id.* Ex. 64, at GSK-ECK-4-5267.

On August 27, 2003, and October 3, 2003, GSK's then-Manager of Global Quality Assurance Cheryl Eckard disclosed "serious quality assurance and compliance problems at [the Cidra Plant]" to the FDA.[9] Am. Compl. ¶ 107. Eckard provided the FDA with a memorandum she

[9] Eckard was later terminated from her position with GSK, which, as discussed below, led to her filing of a False Claims Act suit on February 25, 2004.

prepared in April 2003 identifying "compliance gaps" at the Cidra Plant which the FDA had not identified at the time. *See* GSK Mot. Ex. 66, at Eckard8. She also provided other internal documents addressing manufacturing issues at the Cidra Plant. *See id.* Ex. 65, 49:6-50:10; *id.* Ex. 66. As a result, in October 2003, the FDA's Office of Criminal Investigations executed a search warrant at the Cidra Plant. *See id.* Ex. 6, at 13.

On October 27, 2003, *The Pink Sheet*, a publicly available pharmaceutical regulatory and policy publication, reported that the FDA was investigating the Cidra Plant.[10] The *Pink Sheet* article reported that, on an October 22, 2003, conference call, GSK Pharmaceuticals President David Stout stated that "based on our limited conversations with [the FDA], we don't see any interruption in supply." *Id.* Ex. 67, at 1. GSK Chief Executive Officer J.P. Gardner was also quoted in the article stating "[w]e are very confident in the quality of the supply we are providing at Cidra . . . ." *Id.* The article also noted GSK had disclosed the investigation in its third quarter sales and earnings report for 2003, and had corrected the issues identified in the July 1, 2002, warning letter. *Id.*

The cGMP issues at the Cidra Plant, however, did not end there. Following a further inspection ending on December 2, 2003, the FDA issued another Form 483 notice outlining 16 cGMP violation observations, concerning the Cidra Plant's production of Avandamet, Avandia, Coreg, Paxil tablets, Paxil OS, and Thorazine. *Id.* Ex. 68, at GSK-ECK-7-83380. On November 5, 2004, the FDA issued another Form 483 notice with 12 manufacturing observations regarding the

[10] Plaintiffs "do not dispute that industry publications, newspaper articles, public filings or other communications were matters of public record or otherwise available to [them] generally." Pls.' Resp. to Def.'s Statement of Undisputed Material Facts 39 n.4. However, Plaintiffs note that "discovery in this case did not establish that certain industry publications were read by all Plaintiffs." *Id.* (citing Pls.' Opp'n Ex. 153, at 486:22-487:9 ("[W]e've not found anything to lead us to believe that someone read [the October 2003 Pink Sheet article] or that it was shared.")).

production of Avandamet, Avandia, Coreg, Kytril, Paxil CR, and Paxil OS. *Id.* Ex. 69, at GSK-ECK-51-25986. Also in November 2004, GSK recalled over two million tablets of Paxil IR after post-release testing showed that the tablets were potentially super- or sub-potent. Pls.' Opp'n Ex. 181, at GSK-Cidra-96686. The FDA was notified of the recall on or before December 22, 2004. In regard to the voluntary recall, *The Pink Sheet* reported:

> [T]he recall is not related to the [November 5, 2004, Form 483 notice], the company says. GlaxoSmithKline is working to improve its Cidra, Puerto Rico production facility following receipt of a second FDA "Form 483" manufacturing report . . . GSK "continues to cooperate with the FDA on responding to the observations contained in the two Forms 483," the company said in a Feb. 10 earnings release . . . . The tablets originated in the Cidra, Puerto Rico facility but are not related to the ongoing investigation, GSK said . . . .[11]

GSK Mot. Ex. 93. In response to the Paxil IR recall, GSK created a "Communications Pack," which instructed employees asked about the Paxil IR recall to "[o]nly use the minimum information necessary to satisfy [the] media inquiry." Pls.' Opp'n Ex. 67, at GSK-CIDRA-1160348. The Communications Pack stated that the issue causing the recall of Paxil IR tablets did not affect other products, *see id.* at GSK-CIDRA-1160348 ("Did this issue affect other GSK . . . products? No . . . ."), and that "GSK has every confidence in the products manufactured at [its] Cidra site," *id.* at GSK-CIDRA-1160350.

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[11] The FDA scrutiny of the Cidra Plant was reported in pharmaceutical publications and news reports. *See* GSK Mot. Ex. 87 (noting Bactroban ointment manufactured at the Cidra Plant was recalled after the July 2002 warning letter was issued); *id.* Ex. 88 (same); *id.* Ex. 89 (noting the Cidra Plant, which "produces drugs that make up a fifth of [GSK's] revenue," was under the FDA's scrutiny); *id.* Ex. 90 ("The FDA has launched a probe into a manufacturing plant in Cidra Puerto Rico, owned by UK-based [GSK] . . . The plant in question produces drugs mostly for the US market, including many of GSK's core products."); *id.* Ex. 91 (noting the investigation of the Cidra Plant and that the "Puerto Rican facility manufactures and packages a number of GSK products for the U.S. market"); *id.* Ex. 93 ("The Puerto Rico plant has been under investigation by FDA since October 2003 . . . . 'There can be no assurance as to any remedy the FDA may ultimately seek,' the company acknowledged.").

E. The Paxil CR and Avandamet Recall and Seizure

On February 14, 2005, GSK issued a voluntary recall of specific lots of Paxil CR and Avandamet tablets produced at the Cidra Plant. The Paxil CR lots were recalled due to "a manufacturing defect that [could] result in some tablets splitting apart" and the Avandamet lots were recalled because "some tablets could have a higher level of one of the active ingredients . . . than allowed by the approved regulatory specification." *Id.* Ex. 57, at GSK-ECK-14-4587. GSK advised the FDA of its recall.

GSK prepared an internal Q&A providing "reactive" answers for GSK employees to give when asked about the recall or the FDA inspections at the Cidra Plant. Under the heading "FDA INVESTIGATIONS AT CIDRA (only to be used if asked a direct questions)," GSK advised its employees to state that "[GSK] is continuing production at the Cidra site, and [has] every confidence in the quality of the products we manufacture there," and that "no other products are affected by" the manufacturing issues identified in the voluntary recall for the Paxil CR and Avandamet tablets. *Id.* Ex. 175, at GSK-CIDRA-120918. Furthermore, with regard to questions about whether there were any problems with other products manufactured at the Cidra Plant, GSK advised its employees to state:

> All pharmaceutical manufacturing sites work to regulatory standard for good manufacturing practice. Product quality is paramount for GSK and the company takes its responsibility to manufacture safe and effective product very seriously. Nevertheless minor production issues do arise at our sites and we have standard procedures in place to carry out thorough and effective investigations to determine the root cause of the issue and eliminate any risk to product quality. Like other sites in the GSK network. Cidra has such investigations ongoing.

Id. at GSK-CIDRA-120919.

On March 4, 2005, the FDA and the United States Department of Justice (DOJ) seized the remaining stocks of Paxil CR and Avandamet that were manufactured at the Cidra Plant, due to cGMP violations. *See* Pls.' Opp'n Ex. 57, at GSK-ECK-14-4587. In connection with the seizure,

the FDA filed forfeiture complaints and obtained warrants in the United States District Courts for the Eastern District of Tennessee, the District of Puerto Rico, and the Middle and Eastern Districts of North Carolina. *See generally* GSK Mot. Exs. 71-73. The affidavit attached to the seizure complaint filed in the Middle District of North Carolina noted that "[s]ince 1996, SB Pharmco (dba GlaxoSmithKline), Cidra, Puerto Rico, has failed to achieve consistent compliance with FDA's current good manufacturing practice (GMP) regulation for drugs." *Id.* Ex. 73, at 6. The FDA subsequently issued a press release regarding the seizure noting "[t]he agency is concerned that GSK's violation of manufacturing standards may have resulted in the production of poor quality drug products that could potentially pose risks to consumers." *Id.* Ex. 74. The FDA further noted it was not aware of "any harm to consumers by the products subject to [the] seizure . . . [and] urge[d] patients using the drugs to continue taking their tablets and to talk with their health care provider." *Id.*

The FDA subsequently posted a "Questions and Answers" page regarding the Paxil CR and Avandamet seizure on its website. The FDA explained it:

> [t]ook this action because several inspections of [the Cidra Plant] where these products are made since 2002 revealed significant violations of FDA's current Good Manufacturing Practice (GMP) regulations at this facility. These violations have not been adequately corrected by the firm and could result in production of poor quality drug products that potentially could pose risks to consumers.

Id. Ex. 75, at RegenceCam288681. Four days later, the FDA posted a notice on Med Watch, the "FDA Safety Information and Adverse Event Reporting Program," noting the FDA and DOJ's seizure of Paxil CR and Avandamet. *Id.* Ex. 76.

In response to the FDA's seizure of Paxil CR and Avandamet, pharmaceutical publications covered the seizure and the Cidra Plant in its publications. For example, *The Pink Sheet* noted the "FDA's concerns with the [Cidra Plant] go well beyond the two seized products. All told, the recent 483 reports identify 13 different GSK products to support adverse observations . . . ." GSK

Mot. Ex. 101. Additionally, *The Pink Sheet* noted Paxil CR and Avandamet were vulnerable to seizure because "of the ready availability of replacement therapies [as the] FDA would not typically initiate a seizure against a product like Coreg [another At-Issue Drug] where there is no generic or otherwise substitutable agent."[12] *See id.*

On March 17, 2005, GSK provided its marketing employees with talking points as part of its "Customer Communication Plan" to "proactively inform prescribers" of the Avandamet seizure. The talking points included the follow:

> Doctor, I want to inform you that we are having issues with the production of *Avandamet*:
>
> - First and foremost, we want to assure you that GSK is working with the FDA to resolve these issues as quickly as possible
> - This disruption in *Avandamet* supply is due to manufacturing issues, and GSK believes that these issues do not pose a health risk to patients
> - GSK agrees with the FDA that patients should continue taking their *Avandamet* tablets while supplies last
> - These manufacturing issues do not affect *Avandia* supply; in fact production of *Avandia* has been increased
> - You may choose to transfer patients to comparable doses and dosing regimens of *Avandia* + metformin as separate tablets, providing the option for conversion back to *Avandamet* once supply is re-established . . .
>
> ***Transition:*** "Now, let's discuss the benefits of adding *Avandia* to your patients not at goal on metformin or SU monotherapy."

Pls.' Opp'n Ex. 176, at GSK-CIDRA-480357. An internal Q&A regarding the seizure further instructed GSK's account managers to warn insurers that GSK would "continue to enforce portfolio contracts during the Avandamet and Paxil CR supply disruptions," and that "[d]irecting

[12] Plaintiffs do not dispute that they knew or "had good reason to know of the seizure," Pls.' Resp. to Def.'s Statement of Undisputed Material Facts 54, but assert they "had no information regarding 'the seizure' beyond what was in the public record, and the public record included GSK's assurances regarding the seizure," *id.* at 55, as detailed below.

Avandamet patients to products other than Avandia as the TZD component" would be considered discriminatory conduct. *Id.* Ex. 217, at GSK-CIDRA-3469; *id.* Ex. 218, at GSK-CIDRA-6634.

On May 5, 2005, the FDA entered into a publicly available consent decree with GSK and SB Pharmco. *See* GSK Mot. Ex. 78. The consent decree required a temporary production halt of Avandamet, but did not require GSK to close the Cidra Plant or cease production of any other At-Issue Drug. *Id.* Furthermore, the consent decree did not withdraw FDA approval for any of the At-Issue Drugs. Rather, as a result of the consent decree, GSK hired Quantic Regulatory Services, a third-party auditor, to evaluate the Cidra Plant and its manufacturing process.[13] *Id.* Ex. 79, at GSK-ECK-10-18713.

As part of the consent decree, Quantic provided regulatory oversight from 2005 to 2007. Quantic's audit of the Cidra Plant was an "intense, in-depth, and atypical third-party audit that covered each and every operational area of the Cidra site." Pls.' Opp'n Ex. 31, at 17. Quantic's evaluation was 200 times greater than the typical FDA inspections, and involved a "systems-based cGMP inspection." *Id.* Ex. 60. The consent decree required Quantic to certify, within 120 days, that the "methods, facilities, and controls at [GSK's] Cidra facility are operated and administered in conformity with CGMP requirements." GSK Mot. Ex. 78, at 11. If the Cidra Plant was not

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[13] Two months later, in July 2005, GSK voluntarily recalled an additional nine batches of Paxil IR. As it had done for its previous recalls, on July 12, 2005, GSK issued a "Communications Pack" for its employees regarding the recall. This Communications Pack included statements regarding how the voluntary recall related to the consent decree. Specifically, GSK advised its employees to state that the Paxil IR recall was "an isolated issue concerning one tablet compression machine at the Cidra manufacturing site. It is not connected with past or current FDA investigations at the site, or with the Consent Decree agreed between the FDA and GSK." Pls.' Opp'n Ex. 182, at GSK-CIDRA-44377.

GSK also started "experiencing a new shortage of its Coreg heart drug and diabetes drug Avandamet in the United States, due to processing difficulties at [the Cidra Plant] . . . stem[ing] from earlier manufacturing issues . . . ." Pls.' Opp'n Ex. 183. In an article on the shortage, GSK spokeswoman Nancy Pekarek stated the "new problems occurred because of new documentation mechanisms set in place in response to the consent de[c]ree, which is creating a logjam of getting drugs through the pipeline and out the door." *Id.*

operating in compliance with cGMPs, the consent decree further required Quantic, within 150 days, to submit a written report to the FDA detailing the deficiencies, the corrective measures GSK had taken to address the deficiencies, and the GSK's future plans to correct the deficiencies. *Id.* at 12. Quantic did not issue the 120-day certification, but issued a report detailing 346 outstanding cGMP issues—substantially more than the FDA had found during its five years of investigation at the Cidra Plant during the Relevant Period. *See* Pls.' Opp'n Ex. 61, at GSK-CIDRA-73326.

In September 2005, GSK delivered Quantic's findings to the FDA, along with a report outlining a list of permanent corrective measures and a set of interim controls to "provide ongoing product quality" assurance while it implemented permanent measures. Quantic's findings were designated "Confidential Proprietary Information." Pls.' Ex. 60, at GSK-ECK-10-18715. The Cidra Plant continued operating under Quantic's third-party oversight. In 2007, GSK announced the Cidra Plant would be ceasing manufacturing operations for reasons unrelated to the FDA's regulatory actions and would close in 2009. SB Pharmco was dissolved in 2008 and manufacturing at the Cidra Plant ceased in 2009.

F. Consumer Litigation Related to the Cidra Plant

The cGMP compliance issues at the Cidra Plant resulted in the filing of three consumer lawsuits between 2003 and 2006 relating to GSK's production of Paxil. On December 2, 2003, Caroline Paras filed a putative class action against SmithKline Beecham in the Superior Court of California, Los Angeles County, on behalf of all consumers who purchased "Paxil Oral Suspension and/or Paxil tablets." GSK Mot. Ex. 195, at ¶ 4. The *Paras* action alleged from "June 1997, through and including the present," the drugs were "manufactured in such a manner that the Paxil failed to comply with Good Manufacturing Practices ('GMPs') and therefore failed to have the safety, quality and purity that it purported or was represented to possess." *Id.* ¶ 5. The *Paras* action

asserted claims for, inter alia, breach of implied warranty, negligent or fraudulent misrepresentation or concealment, and unjust enrichment. The case settled in September 2004.

On September 21, 2004, Lois Cole filed another putative class action complaint against SmithKline Beecham in the Superior Court of California, Orange County, on behalf of all consumers who purchased Paxil OS and Paxil CR tablets, asserting the drugs were "manufactured in such a manner that [they] failed to comply with Good Manufacturing Practices." *Id.* Ex. 196, at ¶ 5. The *Cole* action asserted claims for, inter alia, breach of implied warranty, negligent or fraudulent misrepresentation or concealment, and unjust enrichment. On March 23, 2005, Cole filed a second amended complaint, which added allegations relating to the FDA's seizure of Paxil CR and Avandamet. *Id.* Ex. 197.

On March 6, 2006, Alma Simonet filed a putative class action against, inter alia, GSK and SB Pharmco in the United States District Court for the District of Puerto Rico on behalf of all consumers who purchased Paxil CR. The complaint in the *Simonet* action alleged that "[s]ince 1996 Defendants have failed to achieve consistent compliance with FDA's current good manufacturing practice ('GMP') regulations for drugs." *Id.* Ex. 199, at ¶ 13. The *Simonet* plaintiffs brought claims for breach of express and implied warranties, fraudulent misrepresentation, and fraudulent concealment. The plaintiffs' allegations related to the FDA inspections and enforcement action from 2002 up to the 2005 seizure of Paxil CR and Avandamet.

In July 2007, Cole withdrew as the named plaintiff in the *Cole* action and was replaced by Julie Goldenberg. *See id.* Ex. 200, at 3-6. Additionally, Universal Care Inc., a third-party payor, was added as a named plaintiff in the *Cole/Goldenberg* action.[14] *See id.* at 7-8. In February 2009,

[14] A third-party payor is an entity that provides prescription drug benefits to insureds, such as insurance companies, government agencies, unions, and employers.

the *Simonet* action was effectively merged with the *Cole/Goldenberg* action for settlement purposes as Goldenberg and Universal Care were also added as named plaintiffs in the *Simonet* action. On February 27, 2009, the plaintiffs in the *Simonet* action moved for preliminary approval of a class settlement, consisting of a "consumer class" and a "third-party payor class." *Id.* Ex. 202. The third-party payor class included "all entities in the United States and its territories (other than Medicaid, Medicare, and other federally-funded government healthcare programs) that purchased, paid for or reimbursed for (in whole or in part) Paxil CR between April 1, 2002 and March 4, 2005." *Id.* Ex. 203, at ¶ 1. All Plaintiffs in the instant action were members of the third-party payor class in *Simonet*. Plaintiffs received notice of the class action settlement on March 20, 2009, *see id.* Ex. 204, and twenty Plaintiffs retained their current counsel to negotiate with class counsel on their behalf for the settlement.[15] On September 4, 2009, the court approved the settlement agreement and dismissed the action. *See id.* Ex. 213.

G. Eckard's False Claims Act Litigation and Criminal Indictment of SB Pharmco

The cGMP compliance issues also spawned a False Claims Act *qui tam* action. On February 27, 2004, former GSK Manager of Global Quality Assurance Cheryl Eckard filed a False Claims Act whistleblower complaint against GSK relating to the cGMP violations she had observed at the Cidra Plant and reported to the FDA in 2003. *U.S ex rel. Cheryl Eckard v. GlaxoSmithKline, et al.*, No. 04-10375 (D. Mass). On July 17, 2007, Eckard sought leave to file a second amended complaint. In response, GSK moved to seal the second amended complaint. On

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[15] The twenty Plaintiffs are Aetna; Amerigroup; AvMed; Blue Cross Blue Shield Association; Cigna; WellPoint; Blue Cross Blue Shield of Minnesota; Blue Cross Blue Shield of Louisiana; Blue Cross Blue Shield Association; Blue Cross Blue Shield Florida; Blue Cross Blue Shield Kansas; Blue Cross Blue Shield North Carolina; Blue Cross Blue Shield Rhode Island; Blue Cross Blue Shield Tennessee; Government Employees Health Association; HealthNow New York; Group Health Cooperative; KPS Health Plans; Nordian; Priority Health; USAble Mutual Insurance Company d/b/a Arkansas Blue Cross and Blue Shield; and Emblem Health.

July 23, 2007, the Honorable Joseph L. Tauro denied GSK's motion, and on July 24, 2007, the second amended complaint was publicly filed. The second amended complaint detailed various "quality assurance failures and violations of the FDC Act and the CFRs"—including, inter alia, product comingling, inadequate process validation, contamination in products manufactured in the sterile facility, substandard quality and control of water systems, destruction of audit reports, and other cGMP issues. In October 2010, the Government intervened in the suit and the parties settled the action with GSK agreeing to pay approximately $600 million to resolve Eckard's claims.

That same month, the Government filed a one-count Information charging SB Pharmco with interstate shipment of adulterated drugs, in violation of 21 U.S.C. §§ 331(a), 333(a)(2), and 351(a)(2)(B). *See United States v. SB Pharmco Puerto Rico Inc.*, No. 10-10355 (D. Mass. filed Oct. 21, 2010). Similar to the second amended complaint in Eckard's False Claims Act action, the Information alleged SB Pharmco (1) released batches of Kytril which were not produced in a sterile environment, (2) released batches of Bactroban contaminated with bacteria, (3) released Paxil CR tablets capable of splitting apart, and (4) failed to have proper line-clearing procedures to prevent product mix-ups from occurring. SB Pharmco pleaded guilty to the Information pursuant to Federal Rule of Criminal Procedure 11(c)(1)(C), agreeing to a criminal fine of $140 million, a mandatory special assessment of $400, and criminal forfeiture in the amount of $10 million. SB Pharmco and the Government also agreed:

> In light of the pending civil action, *United States of America ex rel. Cheryl Eckard v. GlaxoSmithKline, et al.*, Civil Action No. 04-10375 (D. Mass.), and the Civil Settlement Agreement between SmithKline Beecham Corporation d/b/a GlaxoSmithKline and the United States (which is being signed contemporaneously with this Plea Agreement, and is attached hereto as Exhibit B) which requires the payment of $600,000,000, plus interest, the parties agree that the complication and prolongation of the sentencing process that would result from an attempt to fashion a proper restitution order outweighs the need to provide restitution to any nonfederal victims in this case given that numerous unknown individuals and insurance companies purchased or reimbursed for the drug products in question, and that tracing reimbursements to the various unknown insurance companies and

> patients and determining the apportionment of payment pertaining to the products at issue would be extraordinarily difficult, if not impossible.

Pls.' Opp'n Ex. 15, at 3. Pursuant to a "Side Letter Agreement" date October 21, 2010, GSK admitted no wrongdoing as to SB Pharmco's criminal conduct, acknowledged SB Pharmco's wrongdoing, and agreed to "not make statements inconsistent with this explicit admission of guilt by SB Pharmco to the crime charged in the Information." *Id.* Ex. 17, at 3.

H. The Instant Litigation

On July 15, 2011, approximately one year after GSK settled the *Eckard* action and SB Pharmco pleaded guilty to the one-count Information, Plaintiffs instituted the instant action by filing a Writ of Summons in the Philadelphia County Court of Common Pleas. Plaintiffs filed their Complaint on July 24, 2013. On August 12, 2013, GSK removed the action to this Court. After proceeding through discovery and obtaining the Court's leave, Plaintiffs' filed their Amended Complaint on October 31, 2018, asserting nine claims against GSK: (1) violation of 18 U.S.C. § 1962(c) of the RICO Act; (2) conspiracy to violate § 1962(c) pursuant to § 1962(d) of the RICO Act; (3) conspiracy to violate § 1962(a) pursuant to § 1962(d) of the RICO Act; (4) common law fraud; (5) civil insurance fraud pursuant to 18 Pa. Cons. Stat. § 4117; (6) breach of express warranty pursuant to 13 Pa. Cons. Stat. § 2313; (7) breach of implied warranty of merchantability pursuant to 13 Pa. Cons. Stat. § 2314; (8) unjust enrichment; and (9) negligent misrepresentation. On November 21, 2018, GSK moved for summary judgment on all claims, asserting four global defenses: (A) statute of limitations; (B) lack of causation; (C) lack of injury; and (D) lack of damages as well as individual claim-specific defenses. GSK's motion is now ripe for disposition.

DISCUSSION

Summary judgment shall be granted "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P.

56(a). "Material" facts are those facts "that might affect the outcome of the suit under the governing law." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A factual dispute is "genuine" if "the evidence is such that a reasonable jury could return a verdict for the [non-moving] party." *Id.*

"[A] party seeking summary judgment always bears the initial responsibility of informing the district court of the basis for its motion, and identifying those portions of the [record] which it believes demonstrate the absence of a genuine issue of material fact." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986) (citation and internal quotation marks omitted). To defeat summary judgment, "the non-moving party must present more than a mere scintilla of evidence; there must be evidence on which the jury could reasonably find for the [non-movant]." *Burton v. Teleflex Inc.*, 707 F.3d 417, 425 (3d Cir. 2013) (alteration in original) (citation and internal quotation marks omitted). "Where the record taken as a whole could not lead a rational trier of fact to find for the non-moving party, there is no 'genuine issue for trial.'" *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986) (citation omitted).

A. Statute of Limitations

GSK first argues Plaintiffs' claims are time barred by the applicable statutes of limitations. The statutes of limitations for Plaintiffs' claims are as follows:

> RICO (Counts I – III) – Four years from when Plaintiffs knew or should have known of their injuries. *See Mathews v Kidder, Peabody & Co.*, 260 F.3d 239, 251 n.26 (3d Cir. 2001).
>
> Fraud (Count IV), Civil Insurance Fraud (Count V), Negligent Misrepresentation (Count VI) - Two years from when Plaintiffs knew, or in the exercise of reasonable diligence, should have known of their alleged injuries. *See* 42 Pa. Cons. Stat. § 5524(7).
>
> Unjust Enrichment (Count VII) - Four years from when Plaintiffs knew, or in the exercise of reasonable diligence, should have known that GSK received and retained benefits. *See Juday v. Merck & Co.*, No. 16-1547, 2017 WL 1374527, at *3 (E.D. Pa. Apr. 17, 2017) (citing 42 Pa. Cons. Stat. § 5525)).

> Breach of Express Warranty and Implied Warranty of Merchantability (Counts VIII - IX) - Four years from the date of the breach, subject to tolling only if the warranty extended to a future time, *see* 13 Pa. Cons. Stat. § 2725, or the fraudulent concealment doctrine applies, *see Connaught Labs., Inc. v. Lewis*, 557 A.2d 40, 43-44 (Pa. Commw. Ct. 1989).

Plaintiffs having instituted this action on July 15, 2011, their claims with a four-year statute of limitations are time-barred if they accrued on or before July 15, 2007, and their claims with a two-year statute of limitations are time barred if they accrued on or before July 15, 2009. Under most of the applicable statute of limitations, Plaintiffs' claims accrued when they knew or should have known about their injuries. *See Forbes v. Eagleson*, 228 F.3d 471, 484 (3d Cir. 2000), *cert. denied*, 533 U.S. 929 (2001). The threshold issue for the Court is therefore to determine when Plaintiffs' actually knew or in the exercise of reasonable diligence should have known about their injuries. GSK argues Plaintiffs should have known of their injuries prior to July 15, 2007, because they were on inquiry notice with regard to their claims well before then.

In evaluating an argument based on inquiry notice, the Court applies a two-step test. First, the Court must make an objective inquiry into whether the defendant has met its burden "to show the existence of 'storm warnings'" with respect to the injury in question. *Mathews v. Kidder, Peabody & Co.*, 260 F.3d 239, 253 (3d Cir. 2001). This entails determining whether and when Plaintiffs "had sufficient information of possible wrongdoing to place them on 'inquiry notice' or to excite 'storm warnings' of culpable activity." *Cetel v. Kirwan Fin. Grp., Inc.*, 460 F.3d 494, 507 (3d Cir. 2006) (quoting *Benak ex rel Alliance Premier Growth Fund v. Alliance Capital Mgmt. L.P.*, 435 F.3d 396, 400 (3d Cir. 2006)). Second, if the defendant establishes the existence of storm warnings, "the burden shifts to the plaintiffs to show that they exercised reasonable due diligence and yet were unable to discover their injuries." *See id.* The due diligence inquiry is both subjective and objective. "Whether a party should have known of his injury by exercising reasonable

diligence is a factual determination, and should 'ordinarily' be resolved by a jury." *See Stafford Invs., LLC v. Vito*, Nos. 04-3182, 06-1112, 06-4424, 2008 WL 5062136, at *3 (E.D. Pa. Dec. 1, 2008).

The Court first turns to the question of whether there were adequate storm warnings relating to the pervasive cGMP issues at the Cidra Plant before July 15, 2007, or July 15, 2009. GSK argues Plaintiffs were on inquiry notice of their claims prior to July 15, 2007, due to the media coverage of the Cidra Plant, the three consumer lawsuits filed about Paxil manufactured at the Cidra Plant, and the general FDA enforcement actions with respect to the Cidra Plant. Plaintiffs argue GSK has failed to meet its "heavy" burden to establish the existence of storm warnings regarding the cGMP issues at the Cidra Plant, and even if storm warnings existed, they were dissipated by reassuring statements GSK issued. After careful review of the record, the Court concludes the record demonstrates genuine issues of material fact exist with regard to whether adequate storm warnings existed prior to July 15, 2007, or July 15, 2009.

As noted, the media covered the cGMP issues at the Cidra Plant by reporting on the on-going FDA investigations, including the Form 483 notices, the July 2002 warning letter, and the 2005 seizure action. However, the media coverage of the Cidra Plant was relatively limited in its scope. The coverage primarily focused on Paxil, Avandamet, and Avandia—and very rarely, if at all, mentioned issues pertaining to the fourteen other At-Issue Drugs. Similarly, the three separate individual consumer class actions that were filed regarding the cGMP violations at the Cidra Plant only involved claims for Paxil. *See generally* GSK Mot. Ex. 195 (asserting claims based on Paxil OS and Paxil tablets); *id.* Ex. 196 (asserting claims based on Paxil OS and Paxil CR); *id.* Ex. 199 (asserting claims based on Paxil CR). Further, none of these actions involved anything more than very vague and trivial allegations regarding the cGMP violations at the Cidra Plant during the Relevant Period. *See id.* Ex. 195, at ¶ 5 (alleging the drugs were "manufactured in such a manner

that the Paxil failed to comply with [cGMPs] and therefore failed to have the safety, quality and purity that it purported or was represented to possess"); *id.* Ex. 196, at ¶ 5 (alleging the drugs "were manufactured in such a manner that the Paxil failed to comply with [cGMPs] and therefore failed to have the safety, quality and purity that it purported"); *id.* Ex. 199, at ¶ 19 ("Since 1996 Defendants have failed to achieve consistent compliance with FDA's [cGMP] regulations for drugs").[16]

Moreover, as evidenced by the findings in the Quantic report, the FDA's inspection of the Cidra Plant and cGMP findings were limited, as Quantic identified 346 cGMP violations the FDA had missed. The limited nature the FDA inspections and the fact that the public information regarding the Cidra Plant trickled out over the course of several years, make it unclear as to whether the public information available regarding the Cidra Plant prior to July 15, 2007, was sufficient to generate storm warnings. Furthermore, the information in the Quantic report and regarding the significance of the cGMP violations at the Cidra Plant, appears to have not been publicized or generally accessible until October 2010 when SB Pharmco pleaded guilty to the one-count

[16] The Court acknowledges the cGMP violations relating to Avandia, Avandamet, and Paxil OS received greater media coverage and were the subject of the March 2005 seizure and the basis for the *Cole*, *Paras*, and *Simonet* actions. However, the Court declines to decide whether sufficient storm warnings existed as a matter of law with respect to these drugs because Plaintiffs have produced evidence that GSK sought to limit the publicly available information regarding the FDA actions, and routinely downplayed any cGMP issues by characterizing them as remedied quickly or of minimal concern. What is more, GSK has not set forth evidence demonstrating the *Cole*, *Paras*, and *Simonet* actions, were significantly publicized such that Plaintiffs should have been aware of these actions prior to July 15, 2007. Although Plaintiffs received a notice of settlement in the *Simonet* action, the Court notes that this occurred after July 15, 2007, and only related to the production of Paxil. Given the record before it, the Court declines to take this issue away from the jury. *Cf. Great Rivers Coop. of Se. Iowa v. Farmland Indus., Inc.*, 120 F.3d 893, 898 (8th Cir. 1997) (finding the equity holder had inquiry notice of his claims when he knew that a lawsuit had been filed against the company, and management's reassurances consisted of the self-serving statements that the lawsuit was "ludicrous" and "ridiculous").

Information and GSK settled the *Eckard* action.[17] This information, when coupled with GSK's statements that the issues at the Cidra Plant were either of minimal importance, promptly corrected, or isolated, *see, e g.*, Pls.' Opp'n Ex. 67, at GSK-CIDRA-1160348 ("Did this issue affect other GSK . . . products? No . . . ."), demonstrates that genuine issues of material fact exist as to whether storm warnings sufficient to put Plaintiffs on notice existed on or before July 15, 2007, or July 15, 2009.[18] *See In re DaimlerChrysler AG Sec Lit.*, 269 F. Supp. 2d 508, 514 (D. Del. 2003) ("[W]here there is a mix of information available to the plaintiffs such that any negative statements are tempered by positive statements from a company's management and others, courts have been reluctant to find that the plaintiffs had inquiry notice of their claims.").

Nevertheless, the Court must separately determine whether Plaintiffs' breach of express warranty and implied warranty of merchantability claims are untimely. These claims have a four-year statute of limitations running from the date of the breach, which is not subject to tolling unless

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[17] The Court notes that a second amended complaint in the *Eckard* action was filed publicly in March 2007. However, there is no evidence that the *Eckard* action was widely reported on or that information regarding the *Eckard* action was readily available prior to October 2010.

[18] Because the Court finds genuine issues of material fact exist with regard to whether adequate storm warnings existed on or before July 15, 2007, or July 15, 2009, the Court does not reach the question of whether Plaintiffs exercised due diligence in pursuing their claims. *See Pension Tr. Fund for Operating Eng'rs v. Mortg. Asset Securitization Transactions, Inc.*, 730 F.3d 263, 272 (3d Cir. 2013) ("If defendants carry their burden of establishing the existence of storm warnings, then the burden shifts to the plaintiffs to show that they exercised reasonable due diligence and yet were unable to discover their injuries." (internal quotation marks omitted)). However, the Court notes that whether Plaintiffs exercised due diligence also presents a genuine issue of material fact for the jury to decide. GSK argues Plaintiffs have failed to produce evidence demonstrating their due diligence in following up on reports of problems at the Cidra Plant. But Plaintiffs argue there was nothing they could do to learn of GSK's conduct at the Cidra Plant until it became publicized in October 2010 because insurers (1) have no ability to conduct plant inspections, *see* Pls.' Opp'n Ex. 151, at 415:6-9; *id.* Ex. 156, at 135:23-136:2; and (2) cannot feasibly monitor all regulatory actions given the number of drugs on their formularies, which are manufactured at a multitude of plants, *see id.* Ex. 142, at ¶ 52-57. Resolution of this factual dispute is for the jury at trial. *See Stafford*, 2008 WL 5062136, at *3 ("Whether a party should have known of his injury by exercising reasonable diligence is a factual determination, and should 'ordinarily' be resolved by a jury.").

(A) the "warranty explicitly extends to future performance," 13 Pa. Cons. Stat. § 2725(b), or (B) the fraudulent concealment doctrine applies, *see Connaught Labs.*, 557 A.2d at 43-44 (Pa. Commw. Ct. 1989) ("[A]lthough a plaintiff cannot benefit under the discovery rule in a breach of warranty action, a plaintiff may invoke the doctrine of estoppel in order to extend the statute of limitations if the plaintiff can prove that the defendant caused him to relax his vigilance by some affirmative fraud, deception or concealment of fact."). Because any warranties as to the At-Issue Drugs were breached when the drugs were manufactured at the Cidra Plant between 2000 and 2005, Plaintiffs claims are time-barred unless the warranty extended to future performance or the fraudulent concealment doctrine applies. At the outset, Plaintiffs have not proffered any evidence demonstrating that the express or implied warranties alleged extend to future performance. Therefore, the Court turns to whether the fraudulent concealment doctrine tolls the applicable statute of limitations.

To invoke the fraudulent concealment doctrine, a plaintiff must show "(1) that the defendant actively misled the plaintiff; (2) which prevented the plaintiff from recognizing the validity of her claim within the limitations period; and (3) . . . the plaintiff's ignorance is not attributable to her lack of reasonable due diligence in attempting to uncover the relevant facts." *Cetel*, 460 F.3d at 509. "There must be an affirmative and independent act of concealment that would divert or mislead the plaintiff from discovering the injury." *Bohus v. Beloff*, 950 F.2d 919, 925 (3d Cir. 1991). Once fraudulent concealment is established, "the statute of limitations is tolled until the plaintiff knew or using reasonable diligence should have known of the claim." *Id.* at 925-26 (internal quotation marks and citation omitted).

GSK argues there is no evidence of any of the fraudulent concealment elements because there is no evidence GSK actively misled Plaintiffs, Plaintiffs "never consider[ed] or inquire[d] into manufacturing issues" such that GSK's conduct would have caused them to relax their

vigilance, and Plaintiffs should have known about the facts underlying their alleged injury. GSK's arguments merely point to areas of significant dispute between the parties. First, with respect to whether GSK misled Plaintiffs, Plaintiffs considered manufacturing issues when determining the content of their formularies, and whether Plaintiffs relied on GSK's representations regarding the cGMP compliance of its drugs and the issues at the Cidra Plant, are genuinely disputed factual issues between the parties.[19] *See supra* 5-6, 7, 9-10, 12 (discussing the alleged misleading misrepresentations regarding the conditions at the Cidra Plant and the dispute over how Plaintiffs excluded drugs); *see also*, Pls.' Opp'n Ex. 142, at ¶¶ 33-41 (stating drug manufacturers are in complete control of the manufacturing process and third-party payors must rely on the manufacturer's assurances that their drugs are cGMP compliant). Regarding whether Plaintiffs should have known about their injuries, there are genuine issues of material fact with regard to when Plaintiffs' knew or should have known about their injuries as discussed above. Therefore, genuine issues of material fact as to the application of the fraudulent concealment doctrine preclude the Court from granting summary judgment for GSK based on the statute of limitations, and this issue is0 ripe for trial. *See, e g.*, *Spear v. Fenkell*, No. 13-2391, 2016 WL 7475814, at *5-6 (E.D.

[19] The Court notes there is significant testimony within the record appearing to demonstrate that Plaintiffs did not consider cGMP violations when deciding whether a drug should be removed from their formulary. *See, e.g.*, GSK Mot. Ex. 29, at 227:5-15 ("Q. Did BlueCross BlueShield of Alabama ever remove a drug from the formulary or take any other action to control or restrict utilization of a drug on your formulary because of current good manufacturing practice issues at the manufacturing facility where the drug was made? . . . [A] I'm not aware that we did . . . ."). However, in light of the fact that Plaintiffs have testified that they would have removed the At-Issue Drugs from their formularies had they known how extensive the cGMP violations were at the Cidra Plant, *see e.g.*, Pls.' Opp'n Ex. 154, at 132:15-23 ("KPS would not have paid for drugs that they knew were not made within the FDA standards of good manufacturing practices . . . ."), and that the corporate designees who testified were merely corporate representatives without experience in the P&T committee or PBM committee, *see, e.g* , GSK Mot. Ex. 37, at 96:16-22 ("A. I cannot certify that. Again, I didn't sit on those committees during the period of time that's here, and I don't have minutes to reflect that because they were not available when we ended up walking through to do this search."), the Court finds this is a factual issue the parties must present to the jury at trial.

Pa. Dec. 29, 2016) (denying summary judgment based on an alleged failure to establish fraudulent concealment where fact and credibility issues needed to be resolved at trial).

B. Standing - Injury

GSK alternatively argues Plaintiffs have not produced evidence that they have suffered a legally cognizable injury. To establish standing, a plaintiff must have "(1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision." *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016). At issue here is Plaintiffs' ability to establish an injury in fact.

In denying GSK's motion to dismiss, this Court previously held "Plaintiffs [were] entitled to prove that the nature of GSK's violations had a material impact on the drugs for which they paid." *See* Mem. 11, Nov. 9, 2016, ECF No. 105. GSK asserts they have failed to produce evidence sufficient to establish this injury. GSK Mot. 2. GSK relies on *In re Johnson & Johnson Talcum Powder Products Marketing, Sales Practices & Liability Litigation*, 903 F.3d 278 (3d Cir. 2018)—which was decided after this Court ruled on GSK's motion to dismiss—to support its argument. In *Johnson & Johnson*, a consumer sued a drug manufacturer asserting she received unsafe baby powder, despite being promised safe baby powder, but did not allege she suffered a personal injury from the baby powder. *Id.* at 288. Rather, the plaintiff claimed economic injury. *Id.* at 280-81. The Third Circuit held the plaintiff failed to sufficiently plead such an injury because she did not allege facts that would permit a factfinder to determine, without relying on conjecture, that she failed to receive the economic benefit of her bargain. *Id.* at 287. Specifically, the plaintiff failed to allege the purchase provided her with an economic benefit worth less than the economic benefit for which she bargained. *Id.* at 288. GSK contends *Johnson & Johnson* precludes Plaintiffs' current claims because they failed to produce evidence establishing they received an economic benefit worth less than the economic benefit for which they bargained. *Id.* at 290.

Plaintiffs assert *Johnson & Johnson* is distinguishable from the instant case. Plaintiffs assert, in *Johnson & Johnson*, the plaintiff failed to allege the baby powder she bought was worth less than she paid, and she had a continued desire to continuing purchasing the product in the future despite the health risks. *See id.* at 289. Plaintiffs assert this case is different because they have produced evidence showing the At-Issue Drugs were worthless and they would not have paid for them had they known of the cGMP issues.

Notwithstanding the fact that *Johnson & Johnson* involved a motion to dismiss, insofar as GSK argues Plaintiffs cannot assert a legally cognizable injury, the Court agrees with Plaintiffs that *Johnson & Johnson* does not foreclose their claims. In *Johnson & Johnson*, the Third Circuit held that "to allege . . . an economic injury as a result of simply purchasing [a product], [the plaintiff] must allege that she purchased [a product] that was *worth less* than what she paid for." *Id.* at 287 (emphasis added). In a footnote, the Court noted its holding did not conflict with the Supreme Court of California's holding in *Kwikset Corp. v Superior Court*, 246 P.3d 877 (2011), where the California Court held the plaintiffs could maintain a claim for economic injury against a manufacturer based on their purchase of locksets that were purportedly "Made in the U.S.A." but contained foreign-made parts. 903 F.3d at 290 n.14 (citing *Kwikset*, 246 P.3d at 881). The plaintiffs alleged they had paid more for the locksets than they otherwise would have because they believed the locksets were manufactured in the United States. The court held this was sufficient to state an economic injury. In so holding, it stated, "[f]or each consumer who relies on the truth and accuracy of a label . . . the economic harm is the same: the consumer has purchased a product that he or she paid more for than he or she otherwise might have been willing to pay if the product had been labeled accurately." 246 P.3d at 890. The *Kwikset Corp.* issue is similar to the issue before the Court in this case, as Plaintiffs have allege they paid for drugs believing they were manufactured in compliance with cGMPs but received drugs that were non-compliant and

therefore worth less than what they paid. Thus, *Johnson & Johnson* did not foreclose Plaintiffs' injury theory.

In any event, insofar as GSK contends Plaintiffs have not produced evidence sufficient to demonstrate that they received and economic benefit worth less than the economic benefit for which they bargained, this argument is similarly unpersuasive. In support of its argument, GSK points to: (1) Aetna's corporate designee stating it received "full value" for the At-Issue Drugs, *see* GSK Mot. Ex. 26, at 465:21-467:16; and (2) inconsistencies between Plaintiffs' cGMP expert Phillip Russ's expert report where he stated "all products manufactured at the site between at least 2000 and 2005 lacked any assurance that they were cGMP-compliant and conformed to their represented properties," *see id.* Ex. 2, at 9, and his deposition where he stated "I'm not offering an opinion that all products manufactured at Cidra were not meeting the regulatory range or specification," *see id.* Ex. 8, at 138:21-139:12.

Plaintiffs argue they have produced evidence sufficient to prove that the At-Issue Drugs were worth less than the economic benefit for which they bargained. Specifically, Plaintiffs argue: (1) GSK's own cGMP expert, Ronald Sellon, admitted that a lack of assurance as to the quality of the At-Issue Drugs would render them worthless, *see* Pls.' Opp'n Ex. 20, at 86:8-21("Q. . . . [I]f a manufacturer announced, we're no longer providing an assurance of [safety, identity, strength, purity, and quality] or quality with respect to our drugs, would you expect the consumer to take those drugs? THE WITNESS: . . . [N]o. Q. And would you expect anyone to pay for it? A. Probably not."); and (2) their corporate representatives have consistently testified that failing to follow cGMPs would render a drug valueless, *see, e.g.*, *id.* Ex. 184, at 280:19-25 ("Q. . . . Does Blue Cross Blue Shield of Minnesota believe that drugs produced at the Cidra plant from 1997 to 2006, if they were not manufactured in compliance with current good manufacturing practices, are worthless? A. Yes."). The question of whether Plaintiffs have produced sufficient evidence to

prove their injury thus requires the resolution of genuine issues of material fact and turns on the credibility and weight afforded to the parties' witnesses. *See Virgin Islands v. Henry*, 232 F. App'x 170, 174 (3d Cir. 2007) ("[I]t is axiomatic that [credibility] determinations are the sole province of the jury."). The parties may present this issue to the jury at trial.

C. Causation

Next, the Court turns to GSK's argument that Plaintiffs cannot establish causation because they failed to produce evidence from which a reasonable jury could find that they would have excluded the At-Issue Drugs from their formularies or declined to pay for the At-Issue Drugs had they known about the issues at the Cidra Plant. To succeed on their claims, Plaintiffs must show GSK's acts or omissions were both the "but-for" and proximate cause of their injury. *See Hemi Grp. LLC v. City of New York*, 559 U.S. 1, 9 (2010) (RICO); *Commonwealth v. Ortho-McNeil-Janssen Pharm.*, 52 A.3d 498, 509, 512 (Pa. Commw. Ct. 2012) (fraud and unjust enrichment); *Eckroth v. Pa. Elec., Inc.*, 12 A.3d 422, 427 (Pa. Super. Ct. 2010) (negligence); *Horsom v. Zimmer Holdings, Inc.*, No. 11-1050, 2011 WL 5509420, at *4 (W.D. Pa. Nov. 10, 2011) (breach of warranty).

GSK argues Plaintiffs cannot establish causation because (1) most Plaintiffs had open formularies, which required coverage of all FDA-approved drugs, and (2) Plaintiffs never considered the cGMP violations when determining whether a drug should be covered. GSK relies on two cases to support its argument, *Commonwealth v. Ortho-McNeil-Janssen Pharmaceuticals*, 52 A.3d 498 (Pa. Commw. Ct. 2012), and *Southeast Laborers Health & Welfare Fund v. Bayer Corp.*, 444 F. App'x 401 (11th Cir. 2011). In *Ortho-McNeil-Janssen*, the Commonwealth of Pennsylvania filed suit against the manufacturer of the drug Risperdal, seeking to recover, inter alia, expenses incurred for reimbursing pharmacies for the purchase of Risperdal and other antipsychotic drugs manufactured by the defendant. *See* 52 A.3d at 501. The Court entered a

directed verdict for the manufacturer where the Commonwealth of Pennsylvania alleged, had it "known the true safety and efficacy situation of Risperdal," it would have "considered appropriate restrictions or limitations on Risperdal coverage," *id.* at 508, but failed to provide any evidence to support this assertion at trial, *id.* at 511 ("[O]n the common law element of causation, the Commonwealth did not offer proof that it would have acted differently with knowledge of the 'true' facts."). In *Southeast Laborers*, the third-party payer plaintiff asserted RICO and state law claims arising from the defendant drug manufacturer's failure to disclose risks regarding the drug Trasylol. The Eleventh Circuit upheld the district court's dismissal of the claims against the manufacturer because the plaintiff failed to show how or explain why it made the choice to pay for Trasylol or why manufacturer's alleged concealment of the dangers of Trasylol led the plaintiff to pay for the drug. *See* 444 F. App'x at 410.

Plaintiffs respond by pointing to statements from their corporate representatives and expert witnesses that Plaintiffs would not have provided coverage for the At-Issue Drugs had they known of the cGMP issues at the Cidra Plant. *See, e.g.*, Pls.' Opp'n Ex. 154, at 132:15-23 ("KPS would not have paid for drugs that they knew were not made within the FDA standards of good manufacturing practices . . . ."); *id.* Ex. 188, at 173:10-18 ("You had asked me before if we had known about the issues at the plant, would we have continued to pay for [them]. And if we had known about the egregious conduct at the plant, we would definitely not have paid. . . .") *id.* Ex. 189, at 78:22-79:12 ("Q. . . . So my question is, if CareFirst had known about the manufacturing problems with the drugs, CareFirst would have stopped paying for those drugs; is that correct? A. Yes, If we had known previously); *see also id.* Ex. 150, at 236:15-22; *id.* Ex. 152, at 154:11-16; *id.* Ex. 153, at 588:6-19; *id.* Ex. 159, at 267:6-11; *id.* Ex. 176, at 176:13-23; *id.* Ex. 190, at 72:5-14; *id.* Ex. 191, at 72:16-24; *id.* Ex. 192, at 172:19- 24; *id.* Ex. 193, at 155:21-156:1; *id.* Ex. 194, at 149:20-22. GSK replies asserting Plaintiffs' testimony is self-serving.

There are genuine issues of material fact with respect to causation that preclude the Court from entering summary judgment in GSK's favor on this issue. GSK's assertion that Plaintiffs proffer their own self-serving deposition testimony and expert witnesses to prove causation is misguided. "[T]he issue is not whether [the plaintiff] has relied solely on his own testimony to challenge the [m]otions, but whether [the plaintiff's] testimony, when juxtaposed with the other evidence, is sufficient for a rational factfinder to credit [the plaintiff's] testimony, despite its self-serving nature." *Johnson v. MetLife Bank, N.A.*, 883 F. Supp. 2d 542, 549 (E.D. Pa. 2012) (citing *Gonzalez v. Sec'y of the Dep't of Homeland Sec.*, 678 F.3d 254, 263 (3d Cir. 2012)). In this instance, considering the evidence as a whole, there is sufficient evidence for a rational factfinder to credit Plaintiffs' testimony, that had they known the extent of the Cidra Plant violations, they would have discontinued coverage or restricted coverage.

Moreover, GSK's reliance on *Ortho-McNeil-Janssen* and *Southeast Laborers* is misplaced. With respect to *Ortho-McNeil-Janssen*, the Court entered a directed verdict after the Commonwealth failed to adduce evidence that it would have acted differently. 52 A.3d at 511. This is in contrast to the current case, where Plaintiffs have testified they would have stopped covering the At-Issue Drugs had they known about the systemic cGMP violations at the Cidra Plant and proffered expert testimony that an insurer would not pay for a drug that is materially non-compliant with cGMPs. *See, e.g.*, Pls.' Opp'n Ex. 152, at 154:11-16; *id.* Ex. 153, at 588:6-19; *id.* Ex. 154, at 132:15-23; *see also id.* Ex. 150, at 236:15-22; *id.* Ex. 159, at 267:6-11; *id.* Ex. 188, at 173:10-18; *id.* Ex. 189, at 78:22-79:12; *id.* Ex. 190; at 72:5-14; *id.* Ex. 191, at 72:16-24; *id.* Ex. 192, at 172:19- 24; *id.* Ex. 193, at 155:21-156:1; *id.* Ex. 194, at 149:20-22; *id* Ex. 176, at 176:13-23. *Ortho-McNeil-Janssen* is thus unpersuasive in the instant matter.

In *Southeast Laborers*, the Eleventh Circuit upheld the dismissal of a third-party payer's RICO claim based on causation where the plaintiff failed to "explain how or why it made the

choice to pay for Trasylol and how or why Bayer's alleged concealment of the dangers of Trasylol led [the plaintiff] to pay for Trasylol." 444 F. App'x at 410. This case is fundamentally different as Plaintiffs have provided evidence that, if they had known about the systemic issues at the Cidra Plant, they would have exercised their power to remove or restrict coverage of the At-Issue Drugs on their formularies. *See, e.g.*, Pls.' Opp'n Ex. 208, at 3-4; *id.* Ex. 186, at ¶ 4 & n.6. Given this testimony, *Southeast Laborers* is inapplicable here. In sum, GSK is not entitled to summary judgment on causation.

D. Damages

The Court turns to GSK's final global defense, which asserts Plaintiffs failed to prove a viable damages claim. GSK makes two arguments in support of its motion. First, GSK attacks Plaintiffs' expert testimony. GSK points to Plaintiffs' marketing expert, Dr. Matthew Perri, who stated one aspect of the value of a drug is measured in terms of utility to customers. GSK Mot. Ex. 177, at 64:2-3 ("Q: [I]sn't [a drug's] utility for customers the benefits to patient health that it provides? A: I think that is . . . part of the value proposition for a drug, yes."). GSK contends Aetna's corporate representative agreed with this statement by stating Plaintiffs received "some value" for the drugs, thereby refuting Plaintiffs "all or nothing" damages argument. *Id.* Ex. 26, at 467:8-16 ("Q: So Aetna got the value for the money that it spent on these medications. Right? . . . A: Aetna got the value of paying for the products while the members were taking the products to make sure that they had the intended effect."). Moreover, GSK argues Plaintiffs' expert opinions do not create a genuine issue of material fact because (A) Dr. Rena Conti's assertion that non-compliant drugs are "non-products" is incorrect as the FDA did not remove the At-Issue Drugs from sale and (B) Dr. Stephen Schondelmeyer asserts no person or insurer would pay for non-compliant drugs but states his analysis is not economic in nature.

Plaintiffs contend their evidence establishes the At-Issue Drugs lacked economic value. Plaintiffs argue their deposition and expert testimony establishes that drugs manufactured with material cGMP violations have no economic value to third-party payers and that drugs only have full value if they are manufactured in material compliance with cGMPs. Pls.' Opp'n Ex. 151, at 549:16-550:10 ("Q. And what did you mean in your response [regarding whether Aetna received value]? A. . . . we were assuming . . . , that if the drugs were manufactured based on [cGMPs], that Aetna would be receiving the value of the products . . . ."); *id.* Ex. 159, at 265:10-16 ("[N]ot following good manufacturing practices would render [drugs] valueless even if they contained the labeled content and could potentially deliver implied outcomes."); *id.* Ex. 184, at 28:19-25 ("Q. . . . Does Blue Cross Blue Shield of Minnesota believe that drugs produced at the Cidra plant from 1997 to 2006, if they were not manufactured in compliance with current good manufacturing practices, are worthless? A. Yes."); *id.* Ex. 185, at 174:21-175:8 ("[W]hat gives a drug worth . . . includes things such as the labeling of the drug and also includes that those drugs will be produced following good manufacturing practices."); *see also id.* Ex. 142, at ¶¶ 65, 71 ("When a manufacturer delivers a medication to the market that is non-compliant, it voids the assurance of quality on which customers rely, and thus voids the value of the product. . . . Non-compliant drugs have no value to third-party payers.").

Initially, GSK's argument regarding the analysis by Drs. Perri, Conti, and Schondelmeyer is more properly considered as a motion to exclude pursuant to *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 597 (1993), as it attacks the reliability of their expert opinions. Because GSK currently has a motion to exclude pursuant to *Daubert*, *see* Mot. to Exclude, ECF No. 202, the Court will address this argument in its decision on that pending motion.

Insofar as GSK argues Plaintiffs' damages calculation is improper because Plaintiffs should have discounted any therapeutic value they received from the noncompliant drugs, this is

necessarily a credibility dispute between the parties' experts. *Compare* Pls.' Opp'n, Ex. 142, at ¶¶ 65, 71 ("When a manufacturer delivers a medication to the market that is 80 non-compliant, it voids the assurance of quality on which customers rely, and thus voids the value of the product. . . . Non-compliant drugs have no value to third-party payers."), *with e.g.*, Pls.' Opp'n Ex. 222, at ¶ 33 ("[I]f a pharmaceutical company knowingly infringes a competitor's patent any sales of that company's infringing products are unlawful. However, these products provide significant value to the patients that use them to treat disease and injury, and often garner substantial volumes of sales."). Resolution of this dispute is for the jury at trial. *See Kaniu v. Dickerson*, No. 12-51, 2013 WL 8460754, at *5 (M.D. Pa. Aug. 1, 2013) ("The respective credibility of competing experts is for a jury to decide." (citing *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254 (3d Cir. 2012)).

Second, GSK asserts Plaintiffs' claimed damages theory is impermissibly speculative. GSK argues Plaintiffs cannot demand damages in the amount of the full price paid for the drugs because the calculation fails to take into account the cost of therapeutic alternatives Plaintiffs would have had to provide, as well as any rebates they may have received for covering the At-Issue Drugs. GSK relies on *Sergeants Benevolent Association Health & Welfare Fund v. Sanofi-Aventis U.S. LLP*, 20 F. Supp. 3d 305 (E.D.N.Y. 2014), and *UFCW Local 1776 v. Eli Lilly & Co* , 620 F.3d 121 (2d Cir. 2010). In *Sergeants*, third-party payors brought various RICO and state law claims against the companies who marketed the drug Ketek, alleging the marketers misrepresented its safety and efficacy and engaged in a vigorous campaign to promote "off-label" uses of the drug. 20 F. Supp. 3d at 328. The defendants moved for summary judgment, asserting the plaintiffs failed to establish proximate cause for their RICO claims because the plaintiffs' had only offered generalized proof that, had physicians known about the safety, they would not have prescribed Ketek for patients and the plaintiffs therefore would not have purchased the drug. In addressing RICO's causation requirement, the Court took issue with the attenuated causal chain, which was

interrupted by the independent actions of prescribing physicians. *Id.* at 327. Further, the record did not demonstrate that physicians immediately stopped prescribing Ketek when information regarding its harm was release. *See id.* The Eastern District of New York granted summary judgment for the defendants and held the chain of causation was too attenuated to be proven by the plaintiffs' generalized proof. *Id.* at 328. In doing so, the Court stated "one cannot use generalized proof to determine the injury to Plaintiffs" because a "determination of the extent of Plaintiffs' financial injury as a result of Defendants deception is complicated by uncertainty as to what alternatives to Ketek would have been prescribed had doctors known of Ketek's true efficacy and side effects." *Id.*

Similarly, in *UFCW Local 1776*, third-party payors that underwrote the purchase of prescription drugs by their insureds brought various RICO and state law claims against the manufacturer of the drug Zyprexa, alleging it had misrepresented the drugs efficacy and side effects to physicians. 620 F.3d at 123. The Second Circuit Court of Appeals held the plaintiffs failed to prove causation where they only proffered generalized proof that, had physicians known about the dangers of Zyprexa, physicians would not have prescribed the drug. *Id.* at 135-36. In doing so, the Second Circuit noted: "showing injury by general proof is precluded by uncertainty about what the alternatives to an 'excess' prescription would have been, and how they would have been distributed amongst the plaintiffs." *Id.* at 135.

Plaintiffs respond stating the issues in *Sergeants* and *UFCW Local 1776*, involved "off-label" marketing specifically targeting doctors, not insurers, where the chain of causation ran through each doctor's decision to prescribe the defendant's drug versus another drug, i.e., a comparative choice. Plaintiffs claim this case is distinguishable because there was no comparative choice, but a "yes or no" choice for Plaintiffs maintaining coverage over the At-Issue Drugs.

The Court is not persuaded by the analysis in *Sergeants* and *UFCW Local 1776*. At the outset, both cases involve discrete issues relating to causation in the unique context of RICO claims as well as the use of generalized proof to prove causation in cases involving representations made to a physician and that physician's choice to prescribe the drug at issue. *See Sergeants* 20 F.Supp.3d at 318-29; *UFCW Local 1776*, 620 F.3d at 135-36. Specifically, *UFCW Local 1776* dealt with interpreting the Second Circuit's previous authority regarding the use of "generalized proof" to prove causation where the case involved the defendant manufacturer's representations to specific doctors and hinged on the doctors' reliance on those representations when choosing a prescription to prescribe for a patient. *See* 620 F.3d at 135-36. Similarly, *Sergeants* involved a causation issue where the chain of causation was "interrupted by the independent actions of physicians." 20 F. Supp. 3d at 327. The Court is therefore not persuaded that *Sergeants* and *UFCW Local 1776*'s claim-specific causation analysis applies to the global damages issue here.

Lastly, to the extent GSK argues Plaintiffs damages calculation should deduct the cost of therapeutic alternatives or any rebates Plaintiffs may have received, this is a decision for the jury to resolve at trial based on an evaluation of the parties' conflicting expert testimony. *Compare* Pls.' Opp'n Ex. 221, at ¶ 43 ("Based on my assessment that spending on prescription drugs cannot be separated from the quality manufacturing assured by the manufacturer and overseen by government regulators, non-compliant prescription drugs have no economic value. Therefore, the appropriate measure of damages in this matter is the total amount paid . . . ."), *with id.* Ex. 222, at ¶ 48 ("Dr. Conti fails to account for rebates received by Plaintiffs after the initial reimbursement of a claim, causing her to overstate Plaintiffs' purchases by approximately 8 percent. She also fails to deduct payments on claims where Plaintiffs served in an administrative role only . . . ."); *see also Bhaya v. Westinghouse Elec. Corp.*, 832 F.2d 258, 262 (3d Cir. 1987) ("Evaluation of witness

credibility is the exclusive function of the jury . . . ."). Therefore, GSK is not entitled to summary judgment on its damages defense.

E. State Law Claims

Having found GSK is not entitled to summary judgment on Plaintiffs' claims based on its global defenses, the Court turns to GSK's individual, claim-specific defenses. The Court finds Plaintiffs' RICO (Counts I – III) and unjust enrichment (Count VII) claims fail as a matter of law. However, Plaintiffs' fraud (Count IV), civil insurance fraud pursuant to 18 Pa. Cons. Stat. § 4117 (Count V), negligent misrepresentation (Count VI), breach of express warranty (Count VIII), and breach of implied warranty of merchantability (Count IX) claims present factual disputes for trial.

1. RICO Claims (Counts I & II)[20]

Plaintiffs bring claims pursuant to 18 U.S.C. § 1962(c)-(d) of RICO Act. Under § 1962(c), it unlawful "for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate . . . commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity or collection of unlawful debt." A claim alleging a pattern of racketeering under § 1962(c) requires proof of the following four elements: (1) the existence of an enterprise engaged in or affecting interstate commerce; (2) the defendant was employed by or associated with the enterprise; (3) the defendant participated, directly or indirectly, in the conduct or the affairs of the enterprise; and (4) the defendant participated through a pattern of racketeering activity that must include at least two racketeering acts. *See Hollis-Arrington v. PHH Mortg. Corp.*, 205 F. App'x 48, 53 (3d. Cir. 2006) (citing *Annulli v. Panikkar*, 200 F.3d 189, 198 (3d Cir. 1999)). To establish the third element of a

[20] Plaintiffs also brought a RICO claim pursuant to 18 U.S.C. § 1962(a) (Count III), but stated at the March 12, 2019, oral argument that they are no longer pursuing this claim. Thus, summary judgment will be granted in GSK's favor on this claim and it will not be further discussed.

§ 1962(c) claim, the plaintiff must show the defendant "participated in the operation or management of the enterprise." *See In re Ins Brokerage Antitrust Lit.*, 618 F.3d 300, 371 (quoting *Reves v. Ernst & Young*, 507 U.S. 170, 179 (1993)).

Under 18 U.S.C. § 1962(d), it is unlawful for any person to conspire to violate subsections (a), (b), or (c) of the statute. To sustain an action under § 1962(d), a plaintiff must prove: (1) the defendant adopted the goal of furthering or facilitating the criminal endeavor, *see Salinas v United States*, 522 U.S. 52, 65 (1997); (2) the conspiracy, if completed, would satisfy all of the elements of either § 1962(a), (b), or (c), *see Rehkop v. Berwick Healthcare Corp* , 95 F.3d 285, 290 (3d Cir. 1996); and (3) an injury resulted from an act related to the conspiracy which is enumerated in § 1961(1), *see Beck v. Prupis*, 529 U.S. 494, 505 (2000).

GSK contends Plaintiffs' §1962(c) claim fail as a matter of law because they cannot prove the existence of a valid enterprise. Plaintiffs assert two enterprise theories: (A) the "Plaintiff Enterprise Theory"; and (B) the "SB Pharmco Enterprise Theory." The Court agrees with GSK that Plaintiffs have failed to establish a legally sufficient enterprise theory.

The Plaintiff Enterprise theory posits that "[e]ach Plaintiff constitutes an enterprise victimized by GSK's misconduct" because "[w]ithout exploiting the infrastructure, systems, and facilities owned by Plaintiffs and operated by their many thousands of employees, GSK could not have effectuated the pervasive, nationwide distribution and sale of the At-Issue Drugs and reaped the enormous, unlawful profits that resulted." Am. Compl. ¶ 180. GSK argues the Plaintiff Enterprise Theory is foreclosed by *Jaguar Cars, Inc. v. Royal Oaks Motor Car Co., Inc.*, 46 F.3d 258 (3d Cir. 1995), in which the Third Circuit has determined enterprise theories where the victim is the enterprise are no longer viable under § 1962(c). Plaintiffs dispute GSK's reading of *Jaguar Cars*, arguing the decision did not categorically rule out victim enterprises, but rather refined the standard for a plaintiff to meet under the "operation and management" test. In Plaintiffs view, the

Plaintiff Enterprise Theory is viable so long as they prove GSK participated in the operation and management of the enterprise.

In *Jaguar Cars*, the Third Circuit stated:

> [A] victim corporation "drained of its own money" by pilfering officers and employees could not reasonably be viewed as the enterprise through which employee persons carried out their racketeering activity. Rather, in such an instance, the *proper enterprise would be the association of employees* who are victimizing the corporation, while the *victim corporation would not be the enterprise*, but instead the § 1962(c) claimant.

46 F.3d at 267 (emphasis added). Although this statement was in dictum, numerous district courts in this Circuit have found the Court of Appeals' reasoning persuasive and have determined the enterprise and the victim may not be the same for § 1962(c) claims. *See, e.g* , *Davis v. Unum Grp.*, No. 03-940, 2011 WL 2438632, at *8 (E.D. Pa. June 17, 2011) ("Recognizing that the 'enterprises' in subsections (b) and (c) play different roles, the Supreme Court [in *National Organization for Women, Inc. v Scheidler*, 510 U.S. 249 (1994)] and Third Circuit [in *Jaguar Cars*] have held that . . . a subsection (c) 'enterprise' can never be a victim of racketeering activity because it is the vehicle through which racketeering activity is committed."); *Simon Prop. Grp., Inc. v. Palombaro*, No. 08-1634, 2009 WL 1549293, at *5 (W.D. Pa. June 2, 2009) ("We agree with defendants that the Court of Appeals for the Third Circuit has clearly stated that a RICO enterprise cannot also be a RICO victim."); *Kaiser v. Stewart*, No. 96-6643, 1997 WL 476455, at *7 (E.D. Pa. Aug. 19, 1997) (citing *Jaguar Cars* for the proposition that "[w]hile the enterprise and the victim may be the same for purposes of § 1962(b), this is not true for § 1962(c) claims" for which "the enterprise and the victim must be separate"). The Court finds the reasoning in *Davis*, *Simon*, and *Kaiser* persuasive.[21] Therefore, *Jaguar Cars* precludes Plaintiffs from proceeding on their Plaintiff

[21] At least one court in this district has found that *Jaguar Cars* has taken a different view, finding *Jaguar Cars* did not foreclose victim enterprise theories for § 1962(c) claims. *See Polymer Dynamics, Inc. v. Bayer Corp.*, No. 99-4040, 2000 WL 1146622, at *5 (E.D. Pa. Aug. 14, 2000)

Enterprise Theory because the victim and enterprise may not be the same under § 1962(c). *See also Vanguard Sav. & Loan Ass'n v. Banks*, No. 93-4627, 1995 WL 379999, at *2 (E.D. Pa. June 27, 1995) (summarizing *Jaguar Cars* and noting "[i]n light of *Jaguar*, . . . it is now clear the proper 'enterprise' in such a case is not the victim corporation, but the association of employees through which the defendant persons conducted their racketeering activity").

Even assuming *Jaguar Cars* did not foreclose Plaintiffs from proceeding on their Plaintiff Enterprise Theory, they have failed to demonstrate proof sufficient to sustain a claim under this theory. Under Plaintiffs' interpretation of *Jaguar Cars*, to prevail on their Plaintiff Enterprise Theory, Plaintiffs must show that GSK "operated or managed" Plaintiffs through its conduct. Plaintiffs contend GSK did so by using pressure to ensure drugs manufactured at the Cidra Plant stayed on Plaintiffs' formularies through threatened financial penalties while concealing conditions at the Cidra Plant, *see* Pls.' Opp'n Ex. 217, at GSK-CIDRA-3469; *id.* Ex. 218, at GSK-CIDRA-6634, and manipulating Plaintiffs internal decision making to ensure Plaintiffs continued to sell their drugs.

The United States Supreme Court's holding in *Reves v. Ernst & Young*, 507 U.S. 170 (1993), is instructive here. In *Reves*, the Supreme Court stated "[a]n enterprise also might be 'operated' or 'managed' by others 'associated with' the enterprise who *exert control over* it as, for example, by bribery." *Id.* at 184 (emphasis added). As a consequence, to succeed on their claim, Plaintiffs must show GSK exerted control over their decision making as to the content of their

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(stating "[a] plaintiff also can be an enterprise or a member of an enterprise"). However, the Court is not swayed by *Polymer Dynamics* as it relies entirely on cases decided prior to the decision in *Jaguar Cars*. *See id.* (citing *U S. Energy Owners Comm. v. U.S. Energy Mgmt. Sys., Inc.*, 837 F.2d 356, 362 (9th Cir. 1988); then *Com-Tech Assocs. v Computer Assocs. Int'l, Inc.*, 753 F. Supp. 1078, 1088–89 (E.D.N.Y. 1990), *aff'd*, 938 F.2d 1574 (2d Cir.1991); then *Prudential Ins. Co. of Am v. U.S. Gypsum*, 711 F. Supp. 1244, 1261 n. 5 (D.N.J. 1989); and then *Temple University v. Salla Bros. Inc.*, 656 F. Supp. 97, 102 (E.D. Pa. 1986)). Further, *Polymer Dynamics* reached its decision with little, if any, analysis. *See id.*

formularies. Plaintiffs cannot satisfy this burden. Despite Plaintiffs' contentions otherwise, aside from evidence that GSK may have fraudulently hidden the extent of the cGMP violations at the Cidra Plant from the public, leading Plaintiffs to continue to pay for the At-Issue Drugs, there is no evidence that GSK actively manipulated or exerted control over the content of Plaintiffs' formularies. Thus, even assuming *Jaguar Cars* did not foreclose them from proceeding on their Plaintiff Enterprise Theory, Plaintiffs have failed to demonstrate proof sufficient to establish an enterprise under that theory.

The Court next turns to, Plaintiffs' SB Pharmco Enterprise Theory, which alleges SB Pharmco was the enterprise GSK used to harm Plaintiffs. To establish RICO liability under § 1962(c), a plaintiff must "prove the existence of two distinct entities: (1) a 'person'; and (2) an 'enterprise' that is not simply the same 'person' referred to by a different name." *Cedric Kushner Promotions, Ltd v. King*, 533 U.S. 158, 162 (2001). The defendant, or "person," and the enterprise must have a certain degree of separation because that a RICO defendant cannot conduct only its "own" affairs. *See id.* Courts within the Third Circuit have held a corporation is not distinct from its "subsidiaries, relatives, agents, and affiliates" for the purposes of § 1962(c). *See, e.g.*, *Friedland v. Unum Grp.*, 50 F. Supp. 598, 604 (D. Del. 2014) (collecting cases).

This rule is subject to a limited "exception" where the plaintiff shows "the parent corporation played a role in racketeering activity which is distinct from the activities of its subsidiary [or affiliate]." *Lorenz v. CSX Corp.*, 1 F.3d 1406, 1412 (3d Cir. 1993). However, this exception has been described as "'narrow,' 'theoretical,' and 'rare.'" *Gasoline Sales, Inc. v. Aero Oil Co.*, 39 F.3d 70, 73 (3d Cir. 1994). It cannot be established by merely showing one affiliate obtained benefits from the other's unlawful activity. *See Polymer Dynamics*, 2000 WL 1146622, at *5.

At the outset, SB Pharmco and GSK are not sufficiently distinct such that SB Pharmco could constitute an "enterprise." Because GSK and SB Pharmco are horizontal corporate affiliates, *see* Pls.' Opp'n Ex. 2, SB Pharmco cannot be generally considered a distinct enterprise in the instant action, *see Friedland*, 50 F. Supp. at 604, unless the "'narrow,' 'theoretical,' and 'rare'" exception to the distinctiveness requirement is satisfied, i.e., if SB Pharmco played a different role in the racketeering activity than GSK. *See Gasoline Sales*, 39 F.3d at 73. However, Plaintiffs have not set forth evidence demonstrating GSK's conduct was sufficiently distinct from SB Pharmco's conduct so as to meet the narrow and rare exception. Plaintiffs argue (1) GSK engaged in fraudulent marketing while SB Pharmco manufactured the non-complaint At-Issue Drugs; and (2) both had distinct corporate structures, i.e., SB Pharmco was a Puerto Rican corporation while GSK was a Delaware limited liability company. Nevertheless, these assertions fail to demonstrate GSK engaged in more than its own corporate affairs or merely obtained benefits from SB Pharmco's unlawful activity. Rather, Plaintiffs' contentions regarding the distinction between GSK and SB Pharmco are belied by their own arguments in this case. *See* Am. Compl. ¶¶ 94 ("Whitaker, Pulman, and other GSK executives were unwilling to acknowledge the gravity of the cGMP violations at the Cidra Plant, and to take the corrective actions that Eckard had recommended . . ."), *id.* ¶ 174 ("[B]y reason of the systemic and longstanding violations of cGMPs at the Cidra Plant, Cidra's and GSK's wrongdoing went far beyond those four drugs and extended Plant-wide to all of the At-Issue Drugs"), *id.* ¶ 175 ("Instead of connecting the problems at the Cidra Plant, GSK fraudulently concealed them and continued to distribute huge quantities of adulterated drugs, fraudulently misrepresented the drugs' quality and other material attributes, and consequently reaped from Plaintiffs billions of dollars in unlawful payments each year."). Plaintiffs therefore fail to satisfy RICO's enterprise-distinction requirement. *See Polymer Dynamics*, 2000 WL 1146622, at *5; *Cedric Kushner Promotions*, 533 U.S. at 163 (2001). Plaintiffs' having failed to

prove the existence of an enterprise, under either the Plaintiff Enterprise Theory or the SB Pharmco Theory, GSK is entitled to summary judgment on Plaintiffs' RICO claims under § 1962(c). *See Hollis-Arrington*, 205 F. App'x at 53 (holding plaintiff must establish the existence of an enterprise to succeed on a RICO claim under § 1962(c)).

Additionally, because they have failed to demonstrate the alleged misconduct satisfies all the elements of § 1962(c), Plaintiffs' § 1962(d) similarly fails. *See Rehkop*, 95 F.3d at 290 (stating to establish liability under § 1962(d), "the conspiracy if completed, would satisfy all of the elements of either § 1962(a), (b), or (c)").

2. Fraud and Negligent Misrepresentation (Counts IV & VI)

Next, Plaintiffs bring common law fraud and negligent misrepresentation claims. Common law fraud and negligent misrepresentation are sister claims under Pennsylvania law as the only difference between them is the mental state the plaintiff must prove to succeed. To prove common law fraud, a plaintiff must establish:

> (1) a representation; (2) which is material to the transaction at hand; (3) made falsely, with knowledge of its falsity or recklessness as to whether it is true or false; (4) with the intent of misleading another into relying on it; (5) justifiable reliance on the misrepresentation; and (6) the resulting injury was proximately caused by the reliance.

Kit v. Mitchell, 771 A.2d 814, 819 (Pa. Super. Ct. 2001). Similarly, to prove negligent misrepresentation, a plaintiff must establish:

> (1) a misrepresentation of material fact; (2) made under circumstances in which the misrepresenter ought to have known of its falsity; (3) with an intent to induce another to act on it; and (4) which results in injury to a party acting in justifiable reliance on the misrepresentation.

Boardakan Rest. LLC v. Gordon Grp. Holdings, LLC, No. 11-5676, 2015 WL 4597970, at *10 (E.D. Pa. July 31, 2015).

GSK argues Plaintiffs have not shown reliance on any statements GSK made with regard to the At-Issue Drugs or the Cidra Plant because Plaintiffs "did not consider manufacturing issues" in deciding what drugs they would include in their formulary. *See* GSK Mot. 44. Plaintiffs assert they have produced sufficient evidence of reliance to withstand summary judgment, citing deposition testimony from their corporate designees and experts that Plaintiffs rely on a drug manufacturer's assurances that its drugs are manufactured in compliance with cGMPs[22] and, if cGMP violations occur, on the drug manufacturer's assurances and statements that the problem will be promptly resolved.[23] Plaintiffs also point to evidence of instances where GSK stated the problems at the Cidra Plant were limited to a small subset of drugs and were being corrected. *See, e.g* , GSK Mot. Ex. 67, at 1 ("GSK says that it closed out the issues related to the warning letter early in 2003"); Pls.' Opp'n Ex. 67, at GSK-CIDRA-1160348 ("Did this issue affect other GSK . . . products? No . . . .").

GSK's argument is duplicative of its causation argument. Pls.' Opp'n 12-13. As the Court previously noted, genuine issues of material fact exist as to (1) Plaintiffs' consideration of cGMPs in determining the content of their formulary, and (2) their reliance on GSK's assurances that the At-Issue Drugs conformed to cGMPs and that the problem's at the Cidra Plant were isolated and corrected. *See supra* Section C. These questions must be resolved by the jury. *See Astech Int'l, LLC v. Husick*, No. 07-5241, 2010 WL 11553184, at *1 (E.D. Pa. Jan. 6, 2010) ("[T]he question of justifiable reliance is most appropriately left to the jury. Reasonableness of reliance involves all

[22] *See, e g* , Pls.' Opp'n Ex. 142, at ¶¶ 33-41 (stating drug manufacturers are in complete control of the manufacturing process and third-party payors must rely on the manufacturer's assurances that their drugs are cGMP compliant); *id.* Ex. 148 (stating "[payers rely] on . . . manufacturers to . . . ensure that the medications that they distribute meet those standards")

[23] *See* Pls.' Opp'n Ex. 142, at ¶ 43 (stating payers "expect that manufacturing problems will be fixed as quickly as possible because the assurance that medications are produced in accordance with FDA requirements is necessary for medications to bring value to the market").

of the elements of the transaction, and is rarely susceptible of summary disposition."). Accordingly, summary judgment is denied as to Plaintiffs' common law fraud and negligent misrepresentation claims.

3. Civil Insurance Fraud (Count V)

Plaintiffs next assert a claim for insurance fraud pursuant to 18 Pa. Cons. Stat. § 4117(a)(2)—Pennsylvania's "Insurance Fraud Statute." Section 4117(a)(2) makes it a crime to:

> [k]nowingly and with the intent to defraud any insurer or self-insured, present[] or cause[] to be presented to any insurer or self-insured any statement forming a part of, or in support of, a claim [containing] any false, incomplete or misleading information concerning any fact or thing material to the claim.

Section 4117(g) affords insurers the right to bring a civil action to recover damages for violations of § 4117(a)(2). A fact is material "if it concerns a subject relevant and germane to the insurer's investigation as it was then proceeding, or if a reasonable insurance company, in determining its course of action, would attach importance to the fact misrepresented." *Wezorek v. Allstate Ins. Co.*, No. 06-1031, 2007 WL 2264096, at *15 (E.D. Pa. Aug. 7, 2007) (citations and quotation marks omitted).

GSK argues § 4117(a)(2) is inapplicable in the instant case because drug manufacturers "do not make 'claims' for insurance coverage and insurers do not make 'claims' payments to them." GSK Mot. 44. Plaintiffs assert § 4117(a)(2) is applicable because it was designed to protect insurers from any type of material fraud relating to the submission of insurance claims. The Court notes that authority applying and interpreting § 4117(a)(2) is sparse in this Circuit. The Court therefore looks to the decision of the United States District Court for the District of Massachusetts in *In re Lupron Marketing & Sales Practices Litigation*, No. 01-10861, 2004 WL 2070883, at *1 (D. Mass. Sept. 16, 2004) for guidance.

In *In re Lupron*, the court held a plaintiff insurer could maintain a cause of action pursuant to § 4117 against a third-party pharmaceutical company where the pharmaceutical company published an inflated average wholesale price for a drug and encouraged medical providers to submit claims based on the inflated price. *See id.* at *2. In so holding, the court noted "the intent of [§ 4117] is to protect insurers from all fraudulent claims, whether directly submitted by an insured, or submitted at the instigation of a third party not directly involved in the claims process." *Id.* Given the broad and remedial nature of § 4117, the Court is persuaded § 4117 applies in the instant case. Moreover, this case is similar to *In re Lupron* insofar as Plaintiffs allege GSK fraudulently sold drugs that did not materially comply with cGMP regulations, causing Plaintiffs to reimburse intermediaries—through claims made and governed by the terms the insurance plans they administered—for the purchase of the At-Issue Drugs. *See also Hepps v. Gen. Am. Life Ins.*, No. 95-5508, 1998 WL 564497, at *3 (E.D. Pa. Sept. 2, 1998) ("The fraud may relate to any statement material to the claim; it need not be a misstatement in the application form."). Therefore, GSK is not entitled to summary judgment on Plaintiffs' § 4117(a)(2).

4. Unjust Enrichment (Count VII)

The Court next turns to Plaintiffs' unjust enrichment claim. To prove unjust enrichment under Pennsylvania law, the plaintiff must prove the following elements: "(1) benefits conferred on defendant by plaintiff; (2) appreciation of such benefits by defendant; and (3) acceptance and retention of such benefits under such circumstances that it would be inequitable for defendant to retain the benefit without payment of value." *Sovereign Bank v BJ's Wholesale Club, Inc* , 533 F.3d 162, 180 (3d Cir. 2008).

GSK contends Plaintiffs' unjust enrichment claim fails as a matter of law because they failed to "quantify the benefit" GSK received from its allegedly improper conduct as Plaintiffs paid for the At-Issue drugs by reimbursing third-party intermediaries. Plaintiffs assert their unjust

enrichment claim may proceed because "unjust enrichment claims do not require a direct relationship between the parties." Pls.' Opp'n 39. This case presents an issue similar to *Ortho-McNeil-Janssen Pharmaceuticals*, 52 A.3d at 498. In that case, the Commonwealth Court of Pennsylvania affirmed the dismissal of the plaintiff's unjust enrichment claim where the plaintiff failed to "quantify the benefit" the defendant received. *Id.* at 513. The Commonwealth Court noted the plaintiff, who paid for the at-issue drugs by reimbursing healthcare providers, failed to "identify any fund retained by the drug manufacturer to which a common law equitable remedy would apply." *See id.*

Similarly here, Plaintiffs have failed to "identify any fund retained by [GSK] to which a common law equitable remedy would apply." *See id.* Plaintiffs do not dispute that they did not pay GSK directly for the At-Issue Drugs. Rather, retail pharmacies purchased prescription drugs from wholesalers, who had purchased them from GSK. Plaintiffs damages calculation, however, is premised solely on how much they paid for the At-Issue Drugs through processing the claims from pharmacies and PBMs. *See* Pls.' Opp'n Ex. 221, at ¶ 43 ("[T]he appropriate measure of damages in this matter is the total paid by each plaintiff for the At-Issue Drugs manufactured at Cidra."). Moreover, Plaintiffs have not produced evidence that the amount they paid in processing claims from pharmacies and PBMs is the equivalent of the benefit GSK received. Like the plaintiff in *Ortho-McNeil-Janssen*, Plaintiffs have failed to quantify the benefit of its reimbursement payments that made its way back to GSK.[24] As a result, Plaintiffs' unjust enrichment claim fails as a matter of law and GSK is entitled to summary judgment on this count. *See Ortho-McNeil-Janssen*, 52 A.3d 513.

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[24] Plaintiffs' argument that unjust enrichment claims do not require a direct relationship between the parties is misguided. The mere fact that a direct relationship is not required to sustain an unjust enrichment claim does not mean Plaintiffs can sustain a claim absent evidence of the unjust benefit GSK received.

5. Breach of Express Warranty and Implied Warranty of Merchantability (Counts VIII & IX)

Finally, the Court turns to Plaintiffs' breach of express warranty and breach of implied warranty of merchantability claims. Both express and implied warranty claims are governed by Pennsylvania statute. *See* 18 Pa. Cons. Stat. § 2313 (providing a cause of action for breach of express warranty); *id.* § 2314 (providing a cause of action for breach of the implied warranty of merchantable goods). A breach of an express warranty exists where a defendant makes "an actual affirmation of fact or a promise," the affirmation of fact or promise "formed the basis of the bargain" between the defendant and the plaintiff, and the product does not conform to that affirmation of fact or promise. *See Jeter v. Brown & Williamson Tobacco Corp* , 113 F. App'x 465, 468 (3d Cir. 2004). A breach of the implied warranty of merchantability exists where the product purchased from the defendant is unfit for its ordinary use. *See Wright v. Ryobi Tech., Inc.* 175 F. Supp. 3d 439, 455 n.5 (E.D. Pa. 2016). The Court begins with an analysis of Plaintiffs' breach of implied warranty claims.

GSK contends Pennsylvania does not recognize breach of implied warranty claims in the context of prescription drugs. In support of its argument, GSK points to cases where patients are harmed by using prescription drugs but were precluded from bringing breach of implied warranty claims against the drug manufacturer pursuant to comment k to § 402A of the Restatement (Second) of Torts. In relevant part, comment k provides:

> There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous.

Restatement (Second) of Torts § 402A cmt. k (1965). Pursuant to comment k, courts in this district have found that breach of implied warranty claims against prescription drug manufacturers are not viable because "the very nature of prescription drugs themselves precludes the imposition of a warranty of fitness for 'ordinary purposes', as each individual for whom they are prescribed is a unique organism who must be examined by a physician who is aware of the nature of the patient's condition as well as the medical history of the patient." *Runner v. Bard*, 108 F. Supp. 3d 261, 267-68 (E.D. Pa. 2015) (quoting *Makripodis v. Merrell-Dow Pharm., Inc.*, 523 A.2d 374, 376-77 (1987)).

Plaintiffs argue Pennsylvania law does not bar implied warranty claims relating to prescription drugs, pointing to cases where patients are harmed by medical devices and were permitted to proceed on breach of implied warranty claims against the medical device manufacturer based on the theory that the device had a manufacturing defect. *See Doughtery v. C.R. Bard, Inc* , No. 11-6048, 2012 WL 2940727, at *7 (E.D. Pa. July 18, 2012) (permitting breach of implied warranty claim to proceed where plaintiff alleged a manufacturing defect).

The parties have not cited, and the Court has not found, any authority addressing implied warranty claims where, as here, an insurer asserts that a drug manufacturer has breached an implied warranty that the drug was manufactured in compliance with applicable standards. Much of the authority the parties cite is inapposite because the decision whether to allow a breach of implied warranty claim to proceed turns on scenarios where a doctor prescribes a drug or medical device for the plaintiff and the plaintiff is physically harmed by its use or side-effects, which directly implicates comment k's guidance. *See, e.g.*, *Runner*, 108 F. Supp. 3d at 263 (seeking redress for injuries sustained during the implementation of a "mesh product" during surgery). This is not the case here as the issue is whether GSK breached a warranty that the At-Issue Drugs were

manufactured in compliance with cGMPs, which therefore rendered them unfit for their ordinary use.

Whether Plaintiffs' breach of implied warranty claim is precluded under Pennsylvania law presents the Court with a close issue with no clear guidance. The instant case, however, is most analogous to *Doughtery v. C.R. Bard, Inc.*, where the Court determined the plaintiff could maintain a breach of implied warranty claim based on a manufacturing defect in a medical device, which allegedly rendered it unfit for its ordinary purpose. *See* 2012 WL 2940727, at *7. The *Doughtery* court reasoned that, because "Pennsylvania law does not preclude a strict-liability claim based on a manufacturing defect, [there is] no basis for declining to recognize a claim for breach of the implied warranty of merchantability where it is based on a manufacturing defect." *See id.* Given that Plaintiffs' claims here are most analogous to a manufacturing defect claim, i.e., GSK breached the implied warranty of merchantability that came with the At-Issue Drugs because they were materially non-compliant with cGMPs, the Court is persuaded by the reasoning in *Doughtery*. Therefore, summary judgment will be denied as to Plaintiffs' breach of implied warranty claim.

Last, the Court turns to Plaintiffs' breach of express warranty claim. GSK argues Plaintiffs cannot maintain this claim because Pennsylvania does not recognize it in the context of prescription drugs. *See* GSK Mot. 44. Federal courts in Pennsylvania are split on whether there is a viable breach of express warranty claim against manufacturers of prescription drugs and devices. *See Doughtery*, 2012 WL 294727, at *8 (collecting cases). In *Doughtery*, the court found that a breach of express warranty claim against drug manufacturers exists under Pennsylvania law. *Id.* In discussing the issue, the court stated:

> A claim for breach of express warranty thus sounds more in contract than in tort. While the reasoning of comment k may prevent certain warranties or promises from being implied by law, [there is] no basis for declining to enforce a contractual promise expressly and voluntarily made by a manufacturer of prescription drugs or devices.

Id.

The courts that have found that Pennsylvania law does not recognize a breach of express warranty claim in the context of prescription drugs or medical devices have relied on the Pennsylvania Supreme Court's decision in *Hahn v. Richter*, 673 A.2d 888 (Pa. 1996). *See Bell v. Boehringer Ingelheim Pharm., Inc.*, No. 17-1153, 2018 WL 928237, at *3 (W.D. Pa. Feb. 18, 2018). In deciding whether a plaintiff could maintain a strict liability failure-to-warn claim, the Pennsylvania Supreme Court in *Hahn* held "where the adequacy of warnings associated with prescription drugs is at issue, the failure of the manufacturer to exercise reasonable care to warn of dangers, i.e., the manufacturer's negligence, is the only recognized basis of liability." *Id.* (quoting *Hahn*, 673 A.2d at 889-90).

The Court is again presented with a difficult decision with compelling arguments on both sides and no clear guidance from the Pennsylvania courts. The Court is nevertheless unpersuaded by the authority relying on *Hahn* to hold that Pennsylvania does not recognize a breach of express warranty claim in the context of prescription drugs. Given the Pennsylvania Supreme Court's caveat in *Hahn* that negligence is the only basis for liability in cases where "the *adequacy of warnings* associated with [a] prescription drug[] *is at issue*," 673 A.2d at 890 (emphasis added), the Court declines to broadly interpret and extend the decision in *Hahn* to the instant case involving breach of express warranty claims. Rather, like the court in *Doughtery*, the Court finds "no basis for declining to enforce a contractual promise expressly and voluntarily made by [GSK]," 2012 WL 294727, at *8, insofar as Plaintiffs seek to establish that GSK made an express warranty

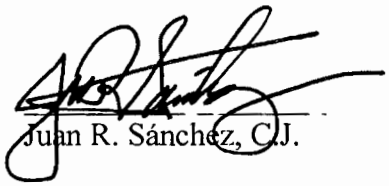
regarding whether the At-Issue Drugs were materially cGMP compliant. Accordingly, summary judgment will be denied as to Plaintiffs' breach of express warranty claim.[25]

CONCLUSION

For the reasons set forth above, the Court will grant GSK's motion for summary judgment in part and deny it in part. Based on the undisputed facts, Plaintiffs' RICO (Counts I – III) and unjust enrichment (Count VII) claims fail as a matter of law, and GSK is entitled to summary judgment as to those claims. However, genuine issues of material fact remain as to Plaintiffs' fraud (Count IV), civil insurance fraud pursuant to 18 Pa. Cons. Stat. § 4117 (Count V), negligent misrepresentation (Count VI), breach of express warranty (Counts VIII), and breach of implied warranty of merchantability (Count IX). GSK's motion for summary judgment will therefore be denied as to those claims.

An appropriate order follows.

BY THE COURT:



Juan R. Sánchez, C.J.

[25] GSK makes a general assertion that Plaintiffs may not maintain their breach of express warranty claim because they were not the patients who purchased the drugs from the pharmacies and therefore are not consumers of the drugs. GSK provides no authority supporting such a narrow interpretation. Moreover, Plaintiffs have alleged, and produced evidence, that drug manufacturers provide an assurance that their drugs are manufactured in material compliance with cGMPs and Plaintiffs rely on that assurance to determine whether a drug will be covered on their formularies and subject to reimbursement. This is sufficient to establish a breach of express warranty claim. *See* 13 Pa. Cons. Stat. § 2313(a)(2) ("Express warranties by the seller are created as follows: . . . (2) Any description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description.").